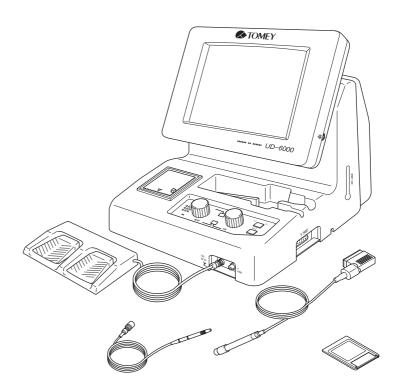


OPERATOR MANUAL

Ultrasound A/B Scanner UD-6000



Read this Operator Manual throughout prior to using this instrument for your correct and safe operation.

If you come up any unclear things while in your operation, please ask Tomey or your local representative.



- Do not use this instrument in an operation procedure other than specified in this Manual.
- · Keep this Manual in a place to where you can easily access.
- Should this Manual be lost, ask your representative for a new copy.



IMPORTANT PRECAUTIONS



- Do not set up this instrument in a place where explosives or inflamables are used or stored. A fire or an explosi on may result.
- Do not remove the cover of the instrument, or you may directly be exposed to high electric voltage.
- Do not disassemble or modify this instrument. You may directly be exposed to high electric voltage.



- Always use the sterilized or disinfected Biometry and A-scan Diagnostic probes for measurement.
- NEVER USE the probe, if it may be subjected to any visible damage on its tip. Such use may not only cause an incorrect measurement, but also damage the cornea.
- Always use the disinfected B-scan Diagnostic probes.
- NEVER USE the B-scan Diagnostic probe, if it may be subjected to any visible damage on its tip. Such use may not only causes an incorrect image, but also damages the cornea.
- Always remove the power cable from the instrument during maintenance to avoid an electric shock.

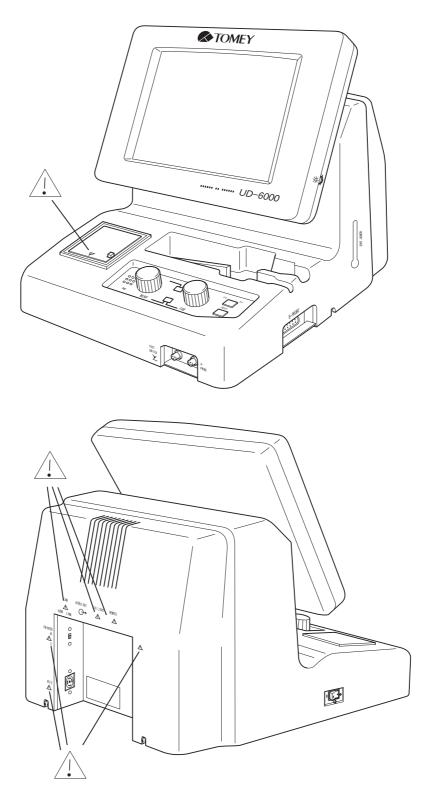


- Do not put water or chemicals on this instrument. An electric shock or a failure may result when they go into the instrument.
- This instrument is designed exclusively for ophthalmic use. DO NOT USE the instrument for any purposes other than ophthalmic.
- DO NOT connect the terminals of the instrument with any cables other than those specified in the manual. Such use may, otherwise, causes to damage the instrument.
- Some of the output terminals are not insulated from inner circuits. Certain connections to the output terminals may break the inner circuits. Be sure to contact TOMEY CORPORATION or our Local distributor when the output terminals are used.



- Do not dirty or hurt the caution marks indicated on the instrument.

 There are one on the front and six on the back.
- In case the caution marks get broken and unclear, contact the place of purchase or TOMEY CORPORATION.



GUIDELINE FOR THIS OPERATOR MANUAL

Components of this Manual

This Manual is composed of the following.

1. PRIOR TO USE

Precautions and confirmations for the installation and usage of this instrument

2. NAMES AND FUNCTIONS OF THE PARTS AND COMPONENTS

Names and functions of parts and components

3. OPERATION PROCEDURE

Necessary information for installing and using this instrument

4. TECHNICAL INFORMATION

Technical information of this instrument, which is convenient for the operation

5. MAINTENANCE AND INSPECTION

Replacement of spare parts for your routine work

6. TROUBLESHOOTING

Countermeasures for troubles

7. SPARE PARTS AND OPTION PARTS

Spare parts and option parts of this instrument

8. SPECIFICATIONS

Specifications of this instrument

9. INDEX

Please refer to the index, as you need.

SYMBOLS USED IN THIS MANUAL

The symbols used in this Manual represent the following meanings.



■ Extremely high risk of serous injury or death unless the instruction is observed.



■ Possibility of serious injury or death unless the instruction is observed.



■ Possibility of minor injury, intermediate handicap or physical loss or damage unless the instruction is observed.



■ Special note describing the company policy directly or indirectly related to the personnel safety or the protection of the property.

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1. PRIOR TO USE



- Be sure to read this Operator Manual throughout before using this instrument for your correct and safe operation.
- Do not use this instrument in any procedure other than specified in this Operator Manual.
- Make sure that there is no equipment in the surrounding of this instrument that generates an intensive magnetic field or such adverse influence that may cause noises, possibly making the instrument unable to correctly diagnose or measure.
- Care shall be given not to place or leave an object on this instrument.

1.1 Operating precautions

This instrument must be used only by skilled operator.



- In biometry measurement check carefully the wave shapes or data variations. In case the data are doubtful perform the measurement again or refer to the result of other tests. If the wrong data are used for IOL selection, surgery may have to be done again.
- Apply the result of IOL Power Calculation to IOL selection after overall evaluation including IOL formula and the result of other tests.
- The values of AXIAL, ACD and LENS obtained by the biometry assistant function can only be used as an assistant information to select the real values in case the biometry values are unstable. Do not directly use these values for IOL calculation.

■ Note the followings when installing this instrument.



- Do not set up in a place where water or chemicals are near the instrument. If those get in the instrument, an electric shock or failure may result.
- Do not set up in a place where chemicals are stored or gas is produced. If those get in the instrument when they are spilled or evaporated, a fire may result.
- Note the frequency, the voltage and the permissible current value (or power consumption) fo the power supply. If the instrument is run by any other power, a fire or an electric shock may result.

- Be sure to connect the power plug to the outlet with a ground cable for three-prong plug. In case of leakage due to failure, an electric shock may result.
- Do not put any heavy stuff on or pinch the power cable, or a fire may result.
- Be sure to connect the power plug all the way in. When the connection gets loose, the metal touches or dust gathers in the terminal of an exposed plug, a fire or an electric shock may result.
- Do not connect any other devices which have different data communication standard. A fire or an electric shock may result.
 Contact the purchasing place when connecting a device to the communication connectors.
- Connect the grounding correctly, or an electric shock may result.
- Do not set up in a place where it gets direct sunlight, the place with high temperature and humidity or the place where the negative effect may occur by air containing dust, salinity, sulfer, etc.
- Set up in a stable place without inclination, vibration, impact, or test result may not be accurate. Also a fire or an accident resulting injury or death may result from falling or dropping.
- Set up in a place far enough from other equipments to avoid malfunction.

Note the followings before use.

- Confirm that this instrument works properly by checking the connection and polarity of switches, dial settings, meters etc.
- Check if all the cables are connected correctly and completely.
- Be careful when using this instrument by other devices working near it. It could caused a danger.
- Confirm that the ground cable is connected properly.
- Confirm that the date indicated by the instrument is correct.

■ Note the followings during use.

- Do not put a bottle with liquid etc. on the instrument. An electric shock or a failure may result.
- Do not lean against the instrument or put any pressure on it. It may fall leading to failure or injury.
- Do not spend too much time for diagnosis ord measurement.
- Always check if there is any abnormality in the instrument and the patient.
- When any abnormality is found in the instrument or the patient, discontinue testing immediately and take appropriate measures.









- Be sure that the patient does not touch the instrument.
- When smoke, odor or abnormal noise comes out of the instrument, turn off the power immediately, pull out the power plug from the outle and contact the place of purchase or TOMEY CORPORATION. Do not let the patient touch the instrument.

■ Note the followings after use.

- Do not put a bottle with liquid or etc. on the instrument. An electric shock or a failure may result.
- When pulling out the power plug from the outlet, pull it out surely from the base of the plug so as not to put any pressure on the cable. When pressure is put on the cable, the core in the power cable may disconnected and an electric shock or a fire may result.
- Do not apply any abnormal stress to the cables by pulling them when there are removed.
- Follow the instructions of " 5.5 Storing of the instrument" regarding the storing place.
- Clean the instrument for the next use.
- If the instrument fails to work properly, discontinue immediately and contact the place of purchase for checks repairs, putting a sign "Out of Order" on the instrument.
 - Do not modify this instrument, or an electric shock or a failure may result. The instrument has a part containing high voltage which may lead to an electric shock. If you touch that part, death or severe injury may result.
 - Replace the fuse after making sure the power plug is pulled out from the outlet, otherwise serious injury or death may result due to an electric shock.
 - Use the accompanying supplies or supplies specified by us for the power cable and the fuse for security reasons. Do not use any accompanying supplies for other devices for security reasons.
 - When the instrument fails to work properly, contact the place of purchase for checks and repairs without tampering with it.
 - Make sure to check this instrument and parts periodically.
 - When the instrument hasn•ft been used for over a month, make sure to check that the instrument works properly and safely without fail before use. See "5.3 Routine maintenance" in this book on how to check.











1.2 Confirmation of accessories

After unpacking the shipment, make sure that the following parts and components are delivered without being damaged.

Should any of the following items be found missing or damaged, ask your local representative or distributer.



- The packaging containers and cushion materials should not be disposed but maintained, since they may be necessary when moving or transporting the instrument.
- When taking out this instrument, remove the buffer materials after putting aside the accessories. Do not hold the monitor to pull out the instrument, or the instrument may fail or break.

● Main unit of the Ultrasound A/B Scanner, UD-6000	. 1
B-mode probe (with case)	. 1
Biometry probe (with protective cap and case)	. 1
Footswitch	. 1
B-mode probe cable guide	. 1
Video printer signal cable	. 1
3P plug power source cord	. 1
Ultrasound diagnosis gel	. 1
Immersion attachment	. 1
B-mode probe attachment	. 1
Attachment for Applanation Tonometer	. 1
Compact flash memory card (with adapter)	. 1
Axial length test piece	. 1
Printer paper roll	. 1
Dust cover	. 1
• Fuses	. 2
Operator Manual of UD-6000 (This booklet)	. 1
DATA Transfer Installation CD	. 1
Operator Manual of DATA Transfer	1

1.3 Explanation of the symbol marks

The symbol marks attached to the instrument imply the following meanings.

: Brightness adjusting volume

[MEMORY CARD] : Memory card slot

[|] : ON side of the power source switch

[O] : OFF side of the power source switch

[FOOT SWITCH] : Footswitch terminal

<u>/</u>

[FIX LIGHT] : Chin Rest AL-1100 fixation lamp power

source plugged to terminal

[VIDEO OUT] : Video signal output terminal

 $\left(\right)$

[REMOTE] : Video printer remote terminal

[LAN] : LAN cable terminal

 $\dot{\mathbb{N}}$

[A-PROBE] : Biometry probe and A-mode probe termi-

nal

[B-PROBE] : B-mode probe terminal

[——] : Fuse

[PRINTER M/C] : Video printer monochrome/color change

switch

[PS/2] : PS/2 terminal

 $\dot{\mathbb{N}}$

1.4 Outline of the operation

This model of UD-6000 is designed an ophthalmic diagnosis instrument, which provides the function acquires the ultrasound cross-sectional image of an eye with the ultrasound oscillators enclosed in the probe, that which acquires the A-scan wave shape, and that which measures the axial length. It is noted that the instrument is in suspension of ultrasound wave transmission.

1.4.1 B-mode image diagnosis

- The B-scan probe, which is connected to the instrument, transmits ultrasound waves into the eyeball, while scanning them in a fan configuration, so that the ultrasound echo is reflected from the organ of the internal part of the eye ball to display its structure in the cross-sectional image.
- The ultrasound beam focus image is controlled with six annulararrayed oscillators arranged concentrically, which ensure a wide range of ultrasound cross-sectional images with high resolution.
- The instrument memorizes 202 images at maximum which can repeatedly play back the images with the most appropriate resolution with the image playback function and the frame forward and reverse function.

1.4.2 Assistant function of biometry

- The assistant function of biometry provides the information to be used for B-scan images, in case the biometry measurement results are not stable with an ordinary biometry instrument.
- This function is not a biometry instrument but an assisting function for biometry.

1.4.3 A-scandiagnosis

 This function is used to identify any affected part if observing Ascan waves.

1.4.4 Biometryfunction

- The probe connected to this instrument transmits ultrasound waves into the internal part of the eyeball, while the ultrasound echo reflected from its anatomy will be received by the same probe.
- The instrument measures the time from the echo for corneal epithelium to that for the object to be measured, with which the length of the tissues is calculated by applying the sound velocity for conversion as set.

$$L = \frac{V \cdot t}{2}$$

L: Axial length

V: Conversion sound velocity

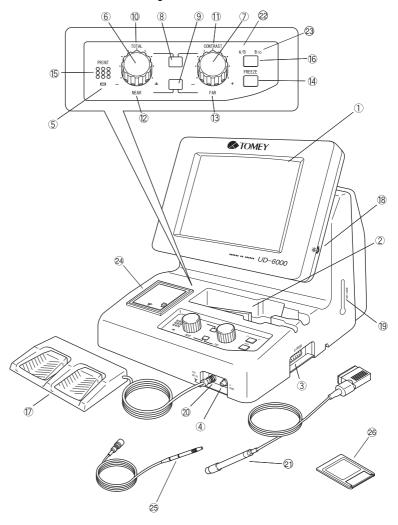
t: Measured time

- This instrument provides the automatic measuring function and the sound monitoring function for the purpose of biometry measurement; therefore, accurate measurement can be obtained regardless of Physician's experience and capability.
- The instrument provides seven standard IOL power calculation formulas; therefore, calculation can be given immediately after axial length measurement has been done.
- The instrument also saves measurement data, corneal radius of curvatures, and implanted IOL data in the memory card. The instrument is also capable of calculating a personal lens constant with saved data for statistical summation.

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2. NAMES AND FUNCTIONS OF PARTS AND COMPONENTS

2.1 Front and right side views and probes



① Monitor/Touch Panel Display

Ultrasound images, waveforms, and various data are displayed and used for operation.

2 Probe Holder

The probe is kept in this holder.

3 B-scan probe terminal

The B-scan probe is connected.

4 A-scan probe terminal

The biometry probe and the A-scan probe are connected.

⑤ Power Indicator

The indicator illuminates while the power is on.

⑥ TOTAL · NEAR volume	⑦ CONTRAST · FAR volume	
Volume function select button 1	Volume function select button 2	
10 Total gain indicator	① Contrast indicator	
Near gain indicator	③ Far gain indicator	

<How to adjust gain contrast>

The two adjusting volumes ⑥, ⑦ have their respective type of function, which are selected with the volume function select buttons, 1 ⑧ and 2 ⑨. (These buttons are selectively used only in the state of real time.)

When pressing the volume function select button 1 8, the function of TOTAL · NEAR volume 6 is set at TOTAL GAIN, while that of CONTRAST · FAR volume 7 at CONTRAST, and the total gain indicator 1 and the contrast indicator 1 are lighted up.

When pressing the volume function select button 2 ②, the function of TOTAL · NEAR volume ⑥ set at NEAR GAIN, while that of CONTRAST · FAR volume ⑦ at FAR GAIN, and the near gain indicator ② and the far gain indicator ③ are lighted up.

(14) FREEZE button

<B-scan image diagnosis function/Biometry assistant function/A-scan diagnosis function> Alternately changes over the freeze condition and the real time condition.

<Biometry function>

Measured data is taken in the manual mode.

(15) PRINT button

Used for printing out.

16 A/B-Bio select button

Changes over the image diagnosis function (B-scan diagnosisfunction/biometry sub-function/A-scan diagnosis function) and the biometry diagnosis function

(17) FOOTSWITCH

- <B-scan image diagnosis function/biometry sub-function/A-scan diagnosis function>
- · FREEZE: Changes over the freeze condition and the real time condition.
- · SAVE/PRINT: Displayed data at freeze is saved in the memory card or printed out.
- <Biometry function>
- · FREEZE: Measurement data is taken in the manual mode.
- · SAVE/PRINT: Displayed data is saved in the memory card or printed out.

Brightness adjusting volume

The brightness of the monitor screen is adjusted.

(19) Memory card slot

The memory card should be inserted.

20 Footswitch terminal

The footswitch should be connected.

(21) B-scan probe

Used for the B-scan image diagnosis function and the biometry sub-function.

22 A/B indicator

Lights while in process of the image diagnosis function as being set.

23 Bio-indicator

Lights while in process of the biometry function as being set.

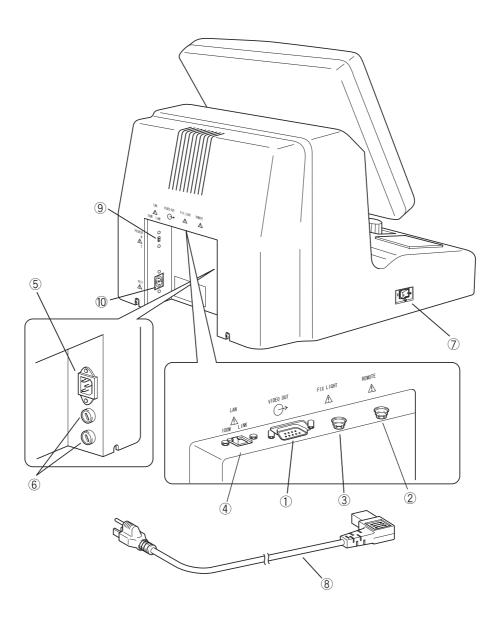
24 Built-in printer

25 Biometry probe

Used for biometry measurement.

26 Memory card

2.2 Back and left side views



1) Video output terminal (VIDEO OUT)

The video signal cable is connected.

② Video printer mode terminal (REMOTE)

The remote cable of the Video Printer is connected.

3 Chin rest (AL-1100) fixation lamp power source plug terminal (FIX LIGHT)

The power source cord for AL-1100 is connected.

4 LAN cable terminal

The LAN cable should be connected.

⑤ Power terminal

The 3P plug power source cord should be connected.

6 Fuse Holder

Fuses are inserted.

7 Power switch

The power can be turned ON/OFF.

8 3P plug power source cord

This cord should be connected to AC 3P power source receptacle.

The video output signal is selected for color or monochrome.

10 PS/2 terminal

The bar code reader and the card reader are connected.

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3. OPERATION PROCEDURE

3.1 Safety precautions



- The biometry probe and the A-scan probe must be sterilized before they are used.
- Do not use the biometry probe and the A-scan probe, if their eye contacting part is damaged, which may otherwise not only affect accurate diagnosis, but may also harm the cornea and the eyelids.
- The B-scan probe must also be sterilized before it is used.
- Do not use the probe with eye contacting part damaged, such use not only affects the images, but also harms the cornea or the eyelids.

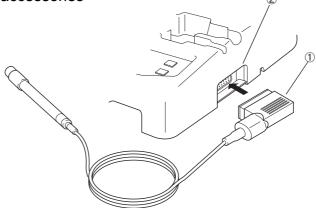


- This instrument is especially designed for the purpose of ophthalmic diagnosis and measurement; therefore, it must not be used for any purposes other than for ophthalmic purposes.
- The connection terminals of this instrument must not be used for any purposes other than specified, which otherwise causes to malfunction the instrument.
- When the probes are not used, store them in their Probe holder.

3.2 Preparation before operation

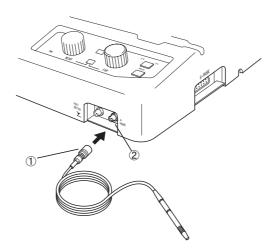
3.2.1 How to connect the accessories

a) B-scan probe



The inserting direction of the connector for the B-scan probe is specified. Insert the probe securely by aligning the inserting direction of its connector ① to the direction of the terminal for B-scan probe connector②.

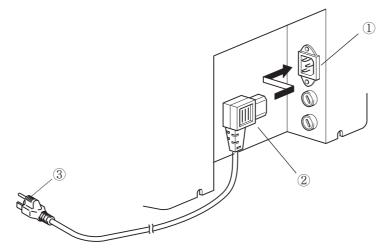
b) Biometry probe



- The insertion direction of the connector for the biometry probe is specified. Securely insert the connector into the terminal until it makes a "click" sound.
 - Make sure that the label applied to the biometry probe is in white color, of which color is used to identify the biometry probe. The probe, if of the other color, is not identified as the biometry probe. The wrong probe does not provide correct biometry operation or correct measurement results.

Next, insert the connector ① of the biometry probe to the connection terminal ② of the biometry probe correctly in the specified direction.

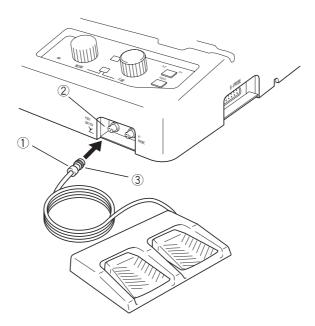
c) Power cord



The insertion direction of the connector for power source cord is specified. Securely insert the cord in specified direction.

Insert the connector ① for power source cord into the terminal ② provided for power source cord in specified direction, by connecting all the 3 pins ③.

d) Footswitch

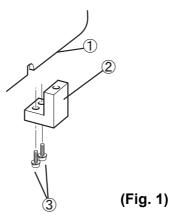


Note ■ The inserting direction of the connector is specified. Securely insert the connector in specified direction as follows:

- 1) Insert the connector ① for footswitch to the terminal for footswitch located in the front panel of the instrument, by aligning the cut in the connector to the terminal ② for footswitch.
- 2) Fix the connector by turning the connector stopper ③ until it stops turning.

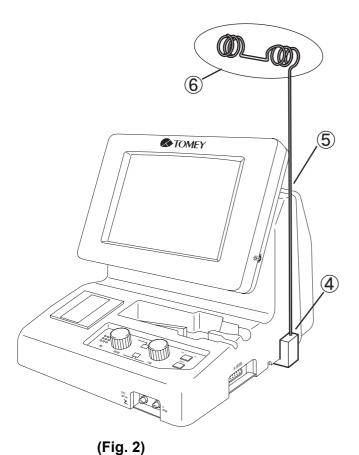
e) Probe cable guide

The cable guide, if used, helps prevent the probe from being damaged when accidentally falling down.

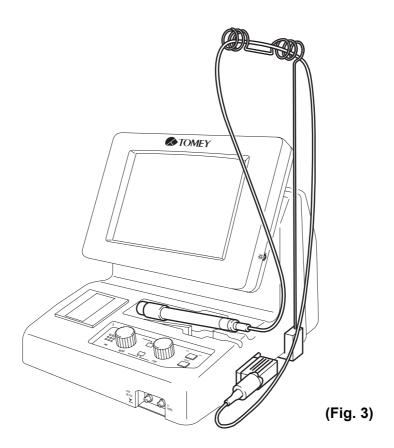


1) Two screw bolt ① openings are provided at the bottom of the right side of the main body of the instrument to securely fix the block ② with these two bolts. (Fig. 1)

Note ■ Since the probe cable guide rotates freely, care must be taken for the end of the guide.



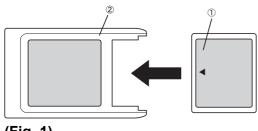
2) Insert the probe cable guide ⑤ into the opening located in the upper part of the block. (Fig. 2)



3) Connect the B-mode probe to the instrument and install the cable by turning along the spiral part ⑥ of the cable guide. (Fig. 3)

f) How to insert and remove the Memory Card

Note
■ Since the memory card is ejected out when removed, press the removing button by holding the end of the card.

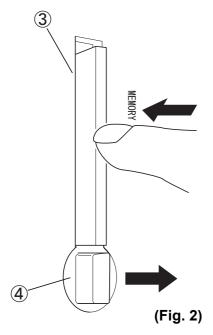


(Fig. 1)

Placing the PC card

Mount the memory card ① in the PC card adapter ②. Carefully insert the memory card in specified direction, in accordance with the Instructions for the Memory Card.

How to insert the memory card



Insert the memory card into the slot ③ located in the rear side of the instrument by turning the face side of the card to your side, until the card ejection button ④ rises to the same level as the card. (Fig. 1) When the memory card is inserted in position, a sound of "beep" is given. In five seconds after this sound, a sound of "beep" is made to confirm that the memory card inserted in position has been recognized by instrument.

How to

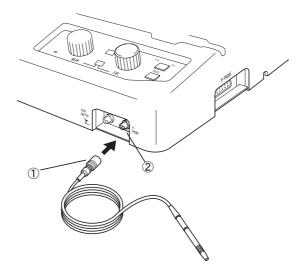
How to remove the memory card

Press the memory card eject button ④ to eject it. (Fig. 3)

(Fig. 3)

3.2.2 How to connect the option parts

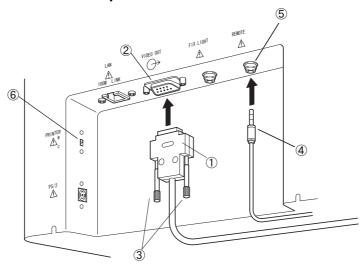
a) A-scan probe



- The connector must be securely inserted in specified position. Insert the connector in specified direction into the position until a click sound is made.
 - Make sure that the color of the label applied to the A-scan probe cable is blue. A color other than blue, if used for the A-scan probe cable, does not correspond to that used for the A-scan probe. The wrong probe, if used for this instrument, may not provide correct diagnosis waves.

Insert the A-scan probe connector ① into the terminal for A-scan probe which is located in the front panel of the instrument, in specified direction.

b) How to connect the video printer



- The direction of the connector for video printer is specified. Sufficiently insert the connector in specified direction, without causing any looseness.
 - And be sure to use specified printer and the cable. This instrument must be connected to the equipment complying with the IEC60601-1 or with the IEC60950-1 of which power source shall be isolated with the isolating transformer, with the use of the video signal cable and the remote cable.
 - 1) Insert the D-sub 15 pin connector ① for video signal cable into the video signal terminal ② located at the rear side of the main unit in specified direction.
 - 2) Secure the fixed screw ③ by turning.
 - 3) Connect another BNC connector for video signal cable to the video printer.

<In case of the monochrome printer>

Connect the BNC connector for green color to the signal terminal for videoprinter. No other connector is required to be connected, since they are not used.

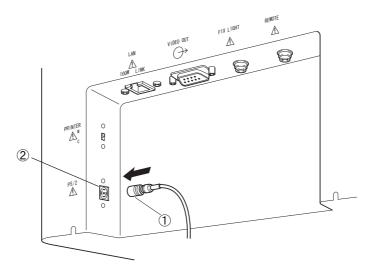
<In case of the color printer>

Connect the red, green, and blue colored BNC connectors to the video signal terminals for video printer. No other cables are required to be connected, since they are not used. Refer to the Instruction Manual for Video Printer for the details of the connection of the Printer.

- 4) Insert the connector 4 for one side of the remote cable into the video printerremote terminal (5) located at the rear side of the main unit.
- 5) Connect another connector of the remote cable to the video printer, inaccordance with the Instruction Manual of the Video Printer. As for the details of connecting procedures, see the Instruction Manual of the Video Printer.
 - <Video printer monochrome/color selection>

In case of the printer which is connected to the instrument is a color printer, change over the video printer monochrome/color select switch © provided at the rear side of the main unit to the side of C, while if connected to the monochrome printer, turn the switch to the side of M.

c) How to connect to the external connection ID inputting device (barcode reader, etc.)



The insertion direction of the connector is specified.

Align the connector to the inserting direction and insert it securely.

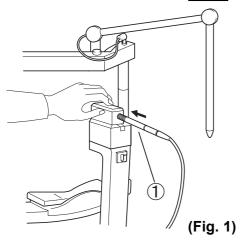
Insert the connector 1 of the external connection ID inputting device (barcode reader, etc.) to the P/S2 connection terminal 2 provided at the back side of the main unit.

3.2.3 How to connect the instrument to the Chin Rest AL-1100

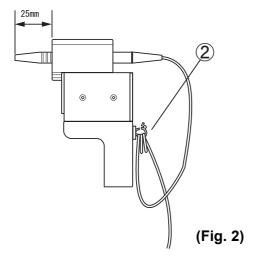
For biometry measurement using the Chin Rest AL-1100, connect the supplied Chin Rest AL-1100 (option device) in the following procedure.

a) How to connect the biometry probe

Note ■ Make sure that the slider part moves smoothly.

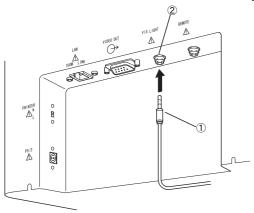


- 1) Carefully insert the biometry probe ① from the side of the slider operator. (Fig. 1) Care must be taken not to damage the eye contacting part of the probe.
- 2) Bundle the probe cord double and hold it with the cord hook ② of the Chin Rest. Twenty centimeters from the probe to the cord hook allows measurement easy, without causing the slider is forcedly pulled with the measuring probe. (Fig. 2)



b) How to connect the power plug of Fixation Lamp for Chin Rest, AL-1100

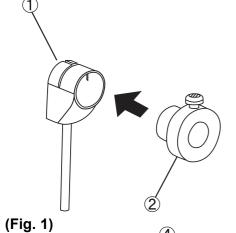
Insert the fixation lamp power plug ① of the Chin Rest into the terminal ② having the identification of "FIX LIGHT".



3-10 3.2 Preparation before operation

3.2.4 How to install the biometry probe to the applanation tonometer

In case of performing biometry measurement with the applanation tonometer, use the attachment for applanation tonometer.



- 1) Hold the prism mounted part ① of the applanation tonometer with your fingers tightly so that it is not moved.
- 2) Insert the attachment for applanation to nometer ② into the prism mounted part from the side of patient. (Fig. 1)
- 3) Insert the biometry probe ③ into the attachment from the examiner's side and fasten the probe with the plastic screws ④ by using the screw driver to secure the biometry probe to the attachment. (Fig. 2)
- 4) In order to prevent the cornea from being compressed, set the measuring knob of the applanation tonometer in the following position.
 - In case the tension of the eye to be measured is lower than 20mmHg, set the meter at 10mmHg.
 - In case the tension of the eye to be measured is above 20mmHg, set at a value of the tension of the eye to be measured minus 10mmHg.

3.2.5 Connection for data communication



- More For data communication with this instrument, networking available system "TIMEY Link" (optional) or test data receiving software "DATA Transfer" (an accessory) is needed.
 - See each of operator manuals of TOMEY Link and DATA Transfer for their setting and operation.
 - In order to connect to TOMEY Link and DATA Transfer, connection setting should be done. See "3.11.2 f) Setting of data communication" for the actual settingl.

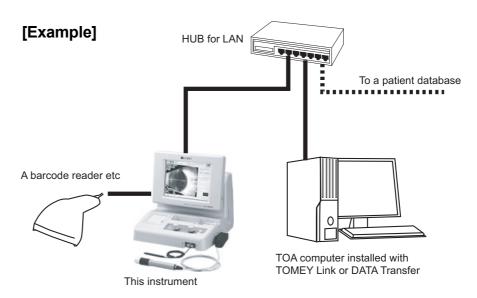
a) LAN wiring



- Be sure to connect this instrument with a computer through a hub. Direct connection with a computer doesn't work properly.
- Be sure to get a permission from your network administrator when performing network setting.
- Confirm the version number of this instrument before use. Version M3.0/G.10 and higher works with DATA Transfer. See "4.5 Software version information" regarding how to confirm the version number.

Connection between this instrument and TOMEY Link server or DATA Transfer needs LAN (Local Area Network). Please prepare the following things.

LAN cable (Straight : Cat.5 and over) : 2 Hub for LAN (100MHz Switching hub is recommended): 1 A TOMEY Link or DATA Transfer installed computer

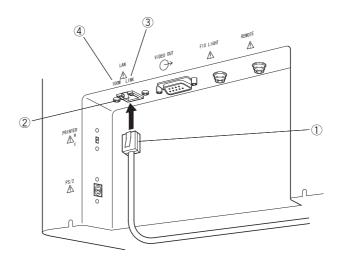


b) Connection to LAN

Notes LAN cable has a direction to be connected.

Be sure to connect in the correct direction.

The connector ① of LAN cable is inserted to the LAN terminal ② on the back of the instrument in the correct direction.



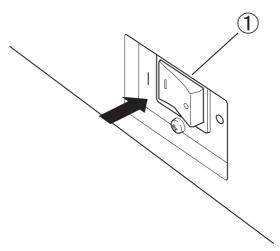
LINK lamp ③ turns on when physical LAN connection is completed at the power on.

When the connection speed is set at 100MHz, 100M lamp ④ turns on. and turns off when connected at 10MHz. These lamps don•ft guarantee that the actual communication is running properly, but just indicating the physical status of connection.

3.3 **B-scan diagnosis**

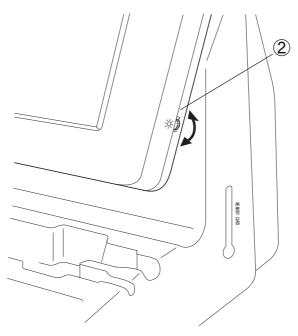
3.3.1 Turing power on and adjustments

a) Turning power on and adjustments

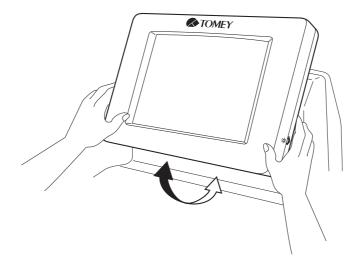


■ When restarting the instrument, turn the power off and Note after a few minutes, turn the power ON again.

1) First, turn the power switch ① provided on the left side of the instrument, by which its main unit and the B-probe are adjusted automatically. If an error is indicated after this adjustment, take appropriate countermeasures by referring to "6. TROUBLE-SHOOTING".



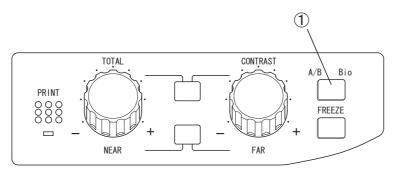
Next adjust the brightness of the monitor with the brightness adjusting volume ② provided on the right side of the monitor, depending on the brightness of the room.



- Notes Sufficient care should be taken not to pinch your fingers when adjusting the angle of the monitor display.
 - Adjust the monitor to such an angle that the display can be watched in the front forward from the examiner. Since the LCD has a narrow visible angle range, the core of the screen may be reversed when watching it from other directions.
 - 3) Adjust the angle of the monitor display as needed. For this adjustment, hold the button of the monitor display and carefully adjust the display angle. Adjusting for the vertical direction only can be given, but not for the horizontal direction.

b) Changing the mode to the B-mode function

Note ■ After switching over the mode to the B-scan diagnosis function, the acquired data can be deleted. Sufficient care must be taken for this deleting operation.



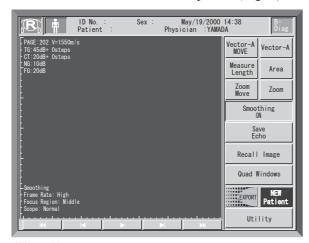
Press the A/B-Bio select button ① for longer than 3 seconds to change the mode to the B-mode image diagnosis function. The operation while making access to the memory card or while in process of LAN communication, no change of the mode can be obtained even by pressing this button.

c) Information displayed in the starting screen



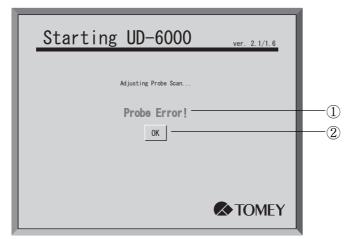
(Fig. 1)

The start screen is displayed immediately after the power has been turned on, which will be followed by calibration of the Bprobe. (Fig. 1)



(Fig. 2)

If the B-probe is properly calibrated, the diagnosis screen (the initial screen) will be displayed. (Fig. 2)

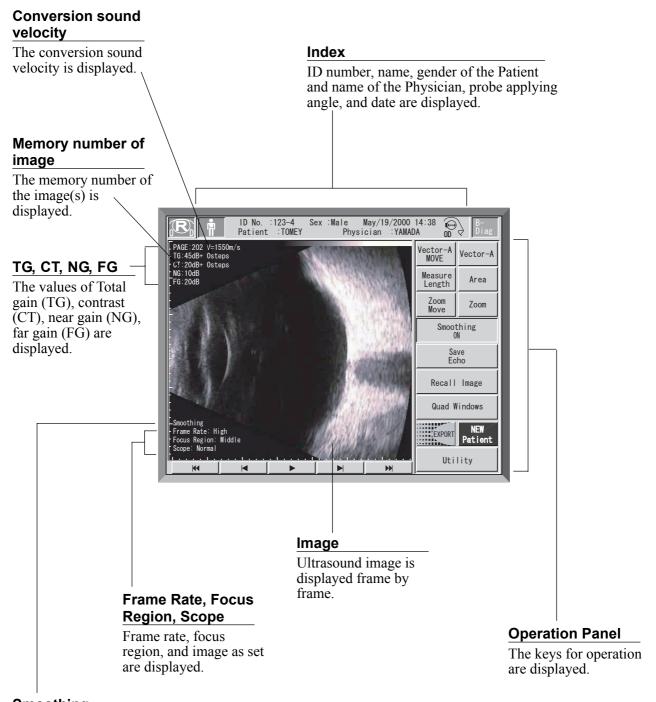


(Fig. 3)

If the B-probe is not properly calibrated, "Probe Error" ① and the OK key ② will be displayed. (Fig. 3) Pressing of the OK key ② will then display the diagnosis screen (the initial screen). (Fig. 3) If the error message is displayed, see "6. TROUBLE-SHOOTING". In the error message is repeatedly displayed after the power has been turned, consult your local representative.

3.3.2 Display information

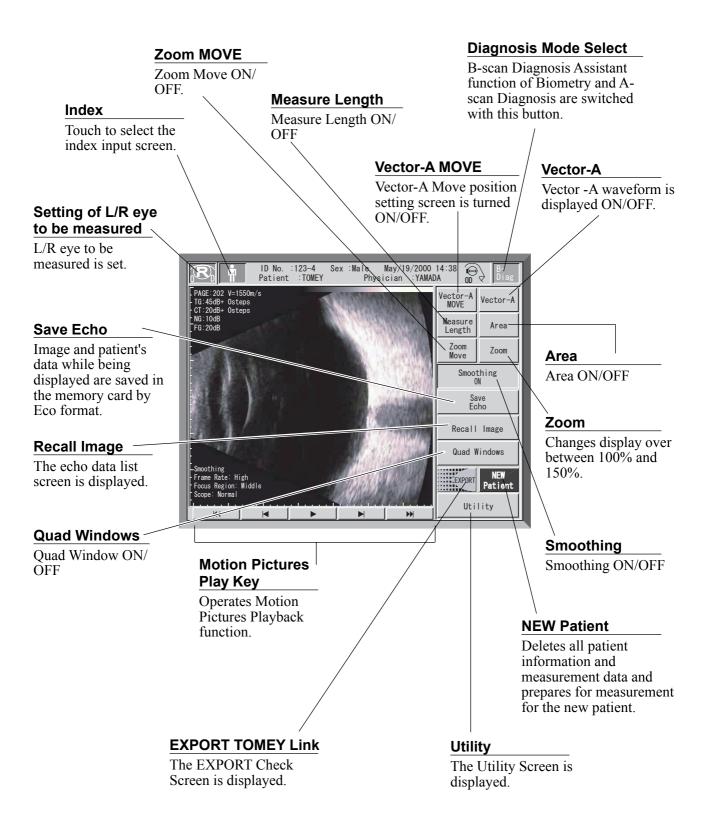
a) Diagnosis images



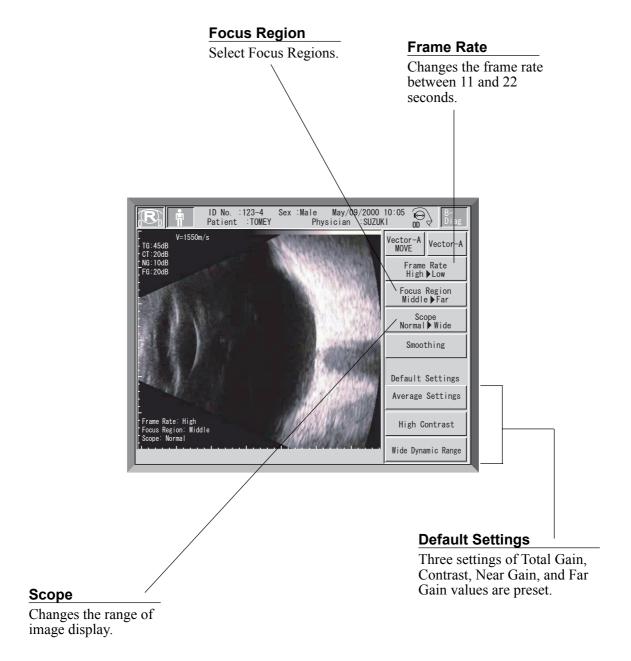
Smoothing

"Smoothing" is displayed while this mode is in active.

b) Main menu at freeze



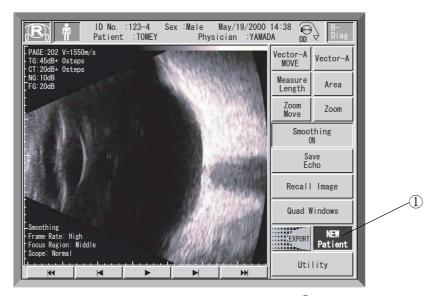
c) Main menu at Scanning



3.3.3 Deletion of all measurement data (Measuring preparation for a new patient)



- Sufficient check must be given before deleting measurement data, since the data if once deleted, will not be restored.
- Be sure to press the NEW Patient key before a new patient is examined and delete all the measurement data. If taking Patient's data without pressing the NEW Patient key, the patient information and the measured data will not be correlated.

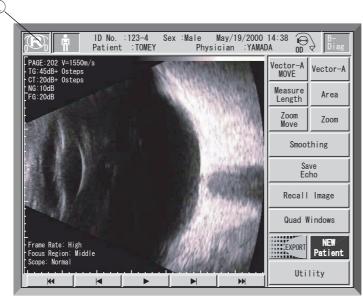


Pressing the NEW Patient key ① for approximately one second for beep in order to delete the patient information (including ID, patient's name, and gender) and image data. Then, the screen will be refreshed. At the same time, the examined eye is set as an undesignated eye.

3.3.4 Inputting of Index data

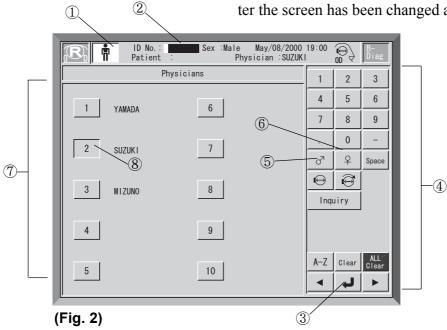
Various index data can be inputted only at freeze. In case of reading patient's ID by using an external connection ID inputting device (such as barcode reader, etc.), see "3.3.5 Inputting index data from external connection ID inputting devices (such as barcode reader, etc.)".

a) Inputting of patient ID number, patient's name, gender, and physician's name



(Fig. 1)

1) Press the Index key ① to change over to the Index Input Screen (Fig. 2). The input portion ② of ID number is highlighted with black/white reversed display immediately after the screen has been changed above.

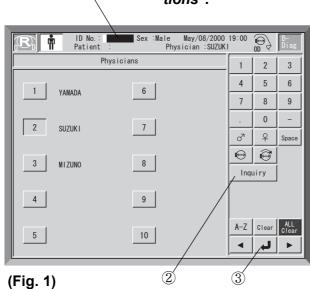


- The input item is changed each time by pressing the Enter Key 3.
- 3) Enter the ID number, patient's name and Physician's name by pressing the number/letter key 4, provided that "." and " " (space) cannot be used for ID number. If automatic inquiry for TOMEY Link has been set, inquiry for patient information will start. See "3.11.2f) Setting of TOMEY Link communications" for automatic inquiry and b) of the sub-paragraph b) of this chapter for patient information.
- 4) Patient's gender is set with the \bigcirc key \bigcirc and \bigcirc key \bigcirc .
- 5) Physician's name is chosen from the list of Physician's names as well as inputted by pressing the keys 8.
- 6) After inputting various data, again press the Index Key ① to the original screen (Fig. 1).

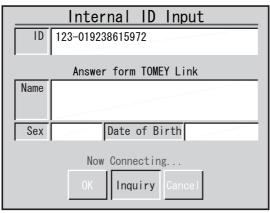
b) Inquiry for patient information (TOMEY Link)

(1)

- Notes In order to use the patient inquiry function, the network available system "TOMEY Link" (optional) is needed. The patient inquiry function cannot be used with the "DATA Transfer" companying with the instrument.
 - As for setting of TOMEY Link server, see the operator manual of TOMEY Link.
 - **■** For connecting to the TOMEY Link, setting for TOMEY Link is required. See "3.8.2 f) Setting of data communications".

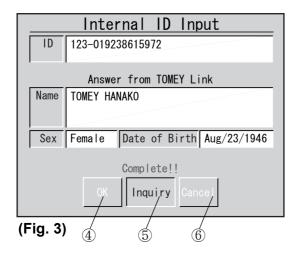


Pressing of the Inquiry key after the ID number has been inputted starts inquiring to the TOMEY Link and next the screen displays the Patient Information Inquiry Screen (Fig. 2).



(Fig. 2)

2) When inquiry for patient information is completed, the message, "Complete!!" will be displayed. (Fig. 3)



- 3) Pressing the Adopt key ④ is reflected for patient information acquired, after which the screen will return to the former screen.
- 4) Pressing the Inquiry key ⑤ restarts inquiry to the TOMEY Link and displays the Patient Information Interim Screen. (Fig. 2)
- 5) Pressing the Cancel key ⑥ returns to the starting screen without proceeding in further operation.
- 6) If inquiry above is not finished in normal condition, the message of "ERROR" is displayed with buzzer sounds. Pressing of the Adopt key ③ is reflected to confirmed patient information only and then the screen will return to the former screen. If the Inquiry key ④ is pressed, inquiry will again be started. And if the Cancel key ⑤ is pressed, the screen is returned to the former screen without reading data.

c) Setting of the eye to be observed

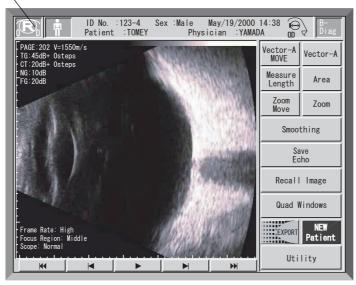


Press the Right/Left key ① to set the eye to be observed. Right and Left for the eye to be observed are changed over every time when this key is pressed.

Note When printing or saving measured data in the memory card or data communicating with the TOMEY Link or DATA Transfer, make sure that the display of the eye in subject is correct.

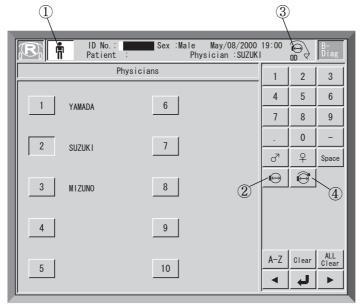
d) Display of the probe applying angle

The B-scan probe angle applied to the eye observed for diagnosed is displayed.



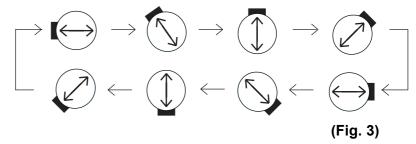
(Fig. 1)

1) Press the Index key ① to change the screen to the Index Input Screen (Fig. 2).

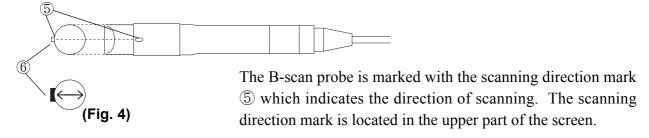


(Fig. 2)

- 2) Press the probe applying angle mark display key ② to display the probe applying angle mark ③. If again pressing the probe applying mark display key, the screen will be the state of "undisplay".
- 3) Press the probe applying angle mark rotation key ④ to set the display angle. Each pressing of this key clockwise turns the probe applying angle mark by each 45 degrees. (Fig. 3)



<Relationship of display image and probe application>



<Probe applying angle mark for scanning direction>

The scanning direction mark of the B-mode probe is identified with the projected part ⑥ of the probe applying angle mark.

4) Pressing the Index key ① returns the screen to the starting screen. (Fig. 1)

3.3.5 Inputting ID number from the external connection ID input device (barcode reader, etc.)

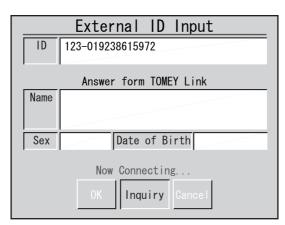


- ানুহে Patient information inquiry function needs TOMEY link (optional) which has networking availability. DATA Transfer accompanying this instrument cannot cover that function.
 - As for setting of the server for TOMEY Link, see the Instructions for TOMEY Link.
 - Setting of connection is necessary for connecting to the TOMEY Link.

See "3.11.2 f) Setting of data communications".

■ Inputting of information from the external connection ID input device (such as barcode reader, etc.) is acceptable only while the following screens are displayed.

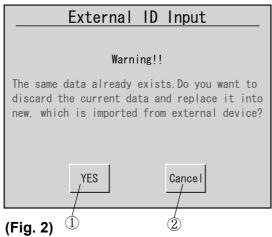
B-scan diagnosis screen	Freeze initial screen
Assistant function of Biometry	Freeze initial screen
A-scan diagnosis function	Freeze initial screen
Axial Length (Biometry)	Measuring screen
	Edit screen
	Measurement Confirmation
	Screen
	IOL calculation screen



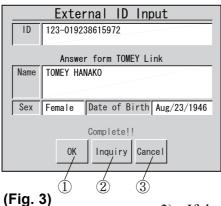
(Fig. 1)

1) When the ID number has been inputted from the external connection ID input device, the Patient Information On-Inquiry Screen (Fig. 1) is displayed. If, however, automatic inquiry to the TOMEY Link has not been set, no inquiry is given. See "3.11.2 f) Setting of data communications".

Note If changing patient information by using the following procedure with the patient information for measurement data (moving image data or similar) as having been inputted, sufficiently make sure that the measurement data which has already been existing is that for the identical patient.



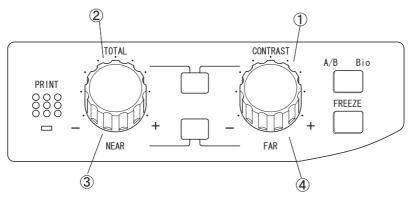
2) If ID input is made from the external connection device with the patient information and measurement data as having already been inputted, the Warning Display Screen (Fig. 2) will be displayed. If deleting such patient data as having already been inputted and reading a new ID number, press the YES key ① to display the External ID Input Confirmation Screen (Fig. 3). Press the Cancel key ② if returning the screen to the former screen without reading the ID number.



- If the automatic inquiry for TOMEY Link has been set, inquiry for patient information will automatically be started. As for the automatic inquiry for TOMEY Link, see "3.11.2 f) Setting of TOMEY Link".
- 4) When the inquiry of patient information has been completed, the message of "Complete" is displayed. (Fig. 3)
- 5) Pressing of the Adopt key ① reflects acquired information to return the screen to the former screen display.
- 6) Pressing of the Inquiry key ② restarts inquiry to the TOMEY Link to display the Patient Information On-inquiry Screen.
- 7) Pressing of the Cancel key ③ returns the screen to the former screen display.
- 8) If inquiry has not normally been finished, the message of "ERROR" will be displayed, with the buzzer as bussing. Then pressing the Adopt key ① only reflects confirmed patient information and returns the screen to the former screen display. Pressing of the Inquiry key ② starts inquiry again. Pressing of the Cancel key ③ returns the screen to the former screen display without inquiry.

3.3.6 Setting of various gain volumes

Fine adjustment of various gain volumes shall be given as observing the ultrasound wave image.



a) CONTRAST volume ①

The contrast of the whole image (white/black contrast) is set.

(Adjustable range: 1 to 60dB)

The higher contrast makes the images having the clearer white and black color definitions, but, at the same time, lowers the penumbra expression which makes it difficult to see delicate changes of the organization. The lower contrast shows the lighter contrast of black and white color definitions which improves the penumbra expression to show the clearer and more delicate changes of the organization.

b) TOTAL volume 2

The echo sensitivity of the total image is set.

(Adjustable range: 1 to 60dB)

The higher sensitivity not only makes the detection of fine echo reflection easier, but also makes the occurrence of unnecessary echoes and artifacts (virtual image which is produced by the reflection and refraction of ultrasound beams) easier. On the other hand, the lower sensitivity suppresses the occurrence of unnecessary echoes and artifacts, but makes it difficult to detect fine reflective echoes.

c) NEAR volume ③

The sensitivity of reflecting echo near the anterior area is set.

(Adjustable range: 1 to 40dB)

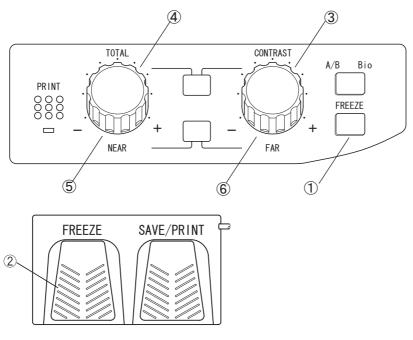
d) FAR volume 4

The sensitivity of reflecting echo near the retina and eyeball rear area is set. (Adjustable range: 1 to 40dB)

3.3.7 Ultrasound image acquisition



- Notes Patient's cooperation is helpful for successful ophthalmic examination. Before going into examination, sufficiently explain the examination procedure to the patient and have him been sufficiently relaxed.
 - When applying the ultrasound gel to the probe, care is to be taken not to cause air in the gel. If any unnecessary echo occurs, add the gel sufficiently.
 - Since pressing of the FREEZE button to release the freeze condition deletes all the moving images which have been acquired, sufficient care must be taken before pressing the FREEZE button.

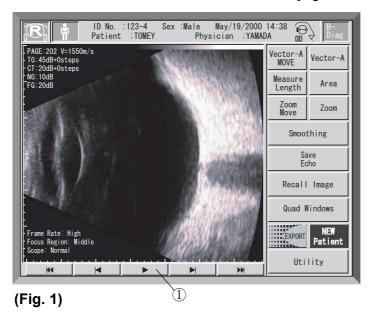


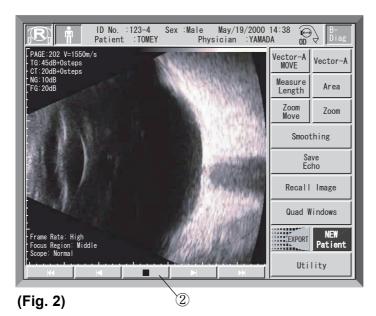
- 1) Press the FREEZE button ① or the FREEZE pedal ② of the footswitch to release the freeze condition.
- 2) Apply an appropriate amount of ultrasound gel to the eye contact part of the B-scan probe.
- 3) Directly place the B-scan probe on the eyelids.
- 4) Adjust the gain volumes of CONTRAST ③, TOTAL ④, NEAR ⑤, and FAR ⑥ for obtaining the optimum images.
- 5) When capturing images, press the FREEZE button ① or the FREEZE pedal ② of the footswitch.

3.3.8 Various functions at the "freeze"

a) Motion pictures playback

The UD-6000 is capable of recording a maximum number of images which can be accommodated in 202 pages and repeatedly played back.

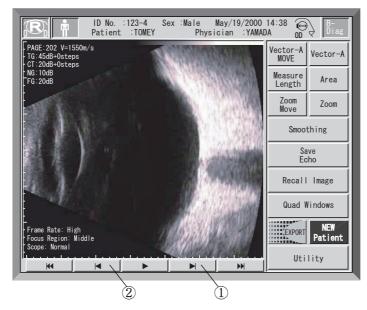




- 1) By pressing the playback key ①, saved images are replayed as a moving picture. While in process of replay, the Stop key ② is shown in the screen. (Fig. 2)
- 2) The replay is stopped at the image of which frame is then replayed when pressing the Stop key.

b) Frame by frame forward/rearward replay

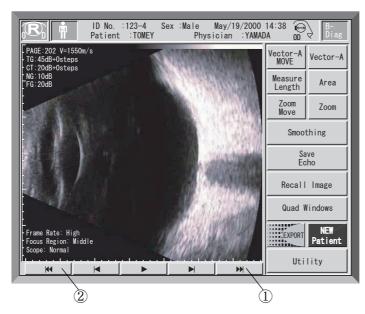
The saved images are displayed page by page.



- 1) Each pressing of the forward (feeding) key ① shows the images page by page in the forward direction.
- 2) Each pressing of the backward (returning) key ② shows the images by page by page in the backward direction. Continuously pressing of either of these keys consecutively feeds the saved images in respected direction.

c) SKIP display

The SKIP display function displays every 5 saved image each time pressing the "skip" button.

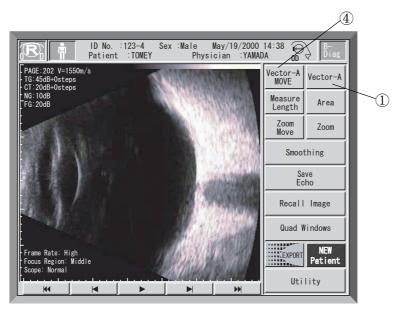


1) Pressing of the Skip Forward key ① will display the image in every fifth page following the page then displaying.

Pressing the Skip Back key ② will display the image in every fifth page receding page then displaying.
 Consecutively pressing either of these keys shows the image in every fifth page in respective direction of forward or backward.

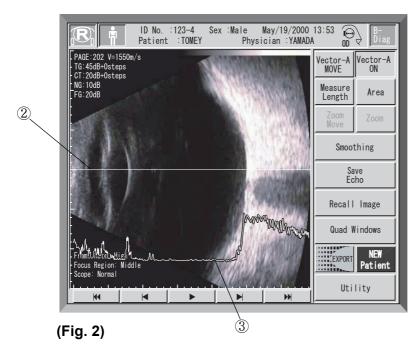
d) Vector-A

This function displays A-scan waveforms of images.

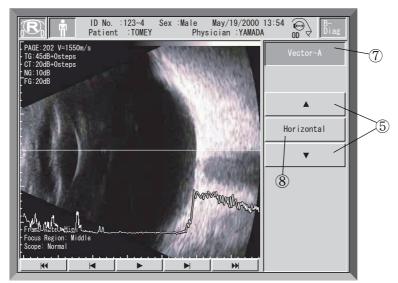


(Fig. 1) <Display of the Vector-A waveform>

1) Pressing of the Vector-A key ① changes the A-scan wave to the "display" vs "no-display". On the condition of "display", the cursor line ② and the A-scan waveform ② in its line position are displayed. (Fig. 2)



<Movement of the Vector-A waveform>

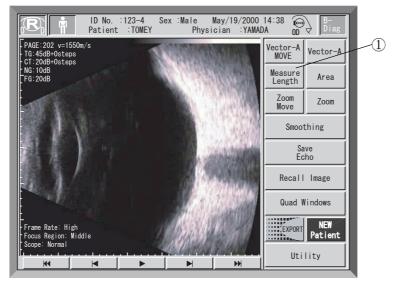


(Fig. 3)

- 1) Press the Vector-A MOVE key ④ (Fig. 1) to change the display to the Vector-A positioning mode. (Fig. 3)
- 2) Next press the UP/DOWN key ⑤ to move the cursor line (yellow) up and down, so that the A-scan waveform (pale blue) in the cursor line is displayed at real time. If the UP/DOWN key is continuously pressed, the cursor line moves continually, while if it is pressed for short time, the cursor line moves by gradation.
- 3) When touching the image, the cursor line position will be moved to the position where the cursor position is touched.
- 4) Press the Horizontal key ⑥ to move the cursor line to the center (default) position.
- 5) When pressing the Vector-A key ⑦, the display will be returned to its former mode with the cursor line and the Ascan waveform as being displayed. (Fig. 2) However, the zooming (See (g) in this section.) cannot be set with the ascan waveform as being displayed. If, also the area calculation function ((f) in this section) and the Quad image display ((L) in this section) are set, the display for cursor line and A-scan waveform will not be displayed, but displayed if these functions are released.

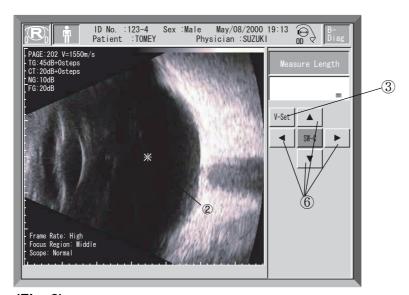
e) Distance measuring

The distance measuring function displays the straight distance between two optional points in the image. This function displays the caliper marks of "+" and "x" in the image, showing the distance between these two points. One caliper mark is red (active caliper) and the other mark is yellow.



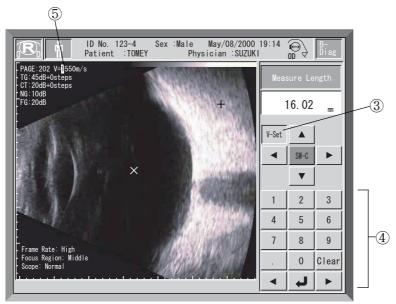
(Fig. 1)

1) Press the Measure Length key ① to change the mode to that for measuring distance, by which the caliper mark ② is shown in the middle of the image. (Fig. 2)



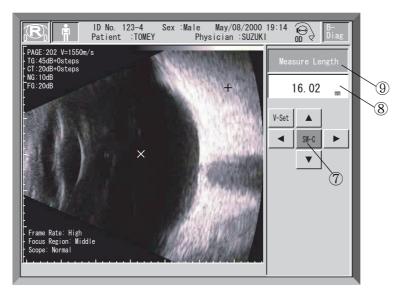
(Fig. 2)

2) Press the V-set key ③ to change the mode to the Sound Velocity Setting Screen. (Fig. 3)



(Fig. 3)

- Press the "Number" key 4 to input a sound velocity which is proper for measuring distance.
- 4) After inputting as above, press the V-set key ③ to return to the previous screen.

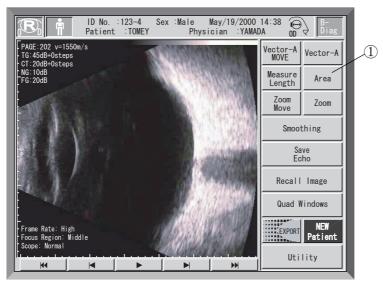


(Fig. 4)

- 5) Press the Move key 6 to move the active caliper.
- 6) Touch the image, so the active caliper will move to the touching position.
- 7) Each time when pressing the SW-C key ⑦, the active calipers are alternately changed.
- 8) Then the straight distance between "+" and "x" is displayed
- 9) Press the Measure Length key (9) to return the mode to the previous display. (Fig. 1)

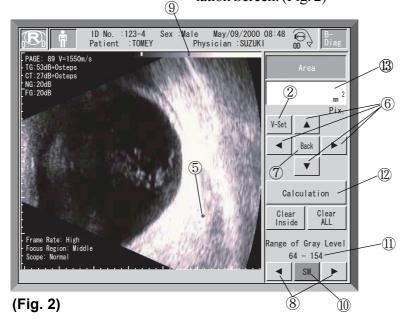
f) Area calculation

This function is used to calculate the area in the region of interest. If an area in the image is touched and enclosed, such enclosed area will be marked with a range of 3 to 64 points. The newest point is colored with red (active point) while the other points are colored white. These points and the active points are automatically connected when they are touched, to make the touched points active. The gradation range to be calculated can also be set. Such area is identified with the red color as the active bar and the light blue bar in the color scale. The instrument detects the critical area corresponding to the gradation range in the enclosure for the purpose of area calculation.

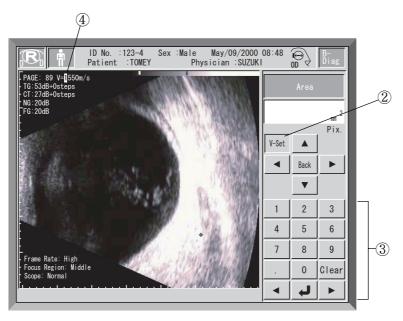


(Fig. 1)

1) Press the Area key ① to change the mode to the Area Calculation Screen. (Fig. 2)

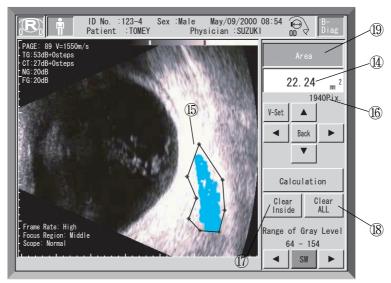


2) Press the V-set key ② to change to the Sound Velocity Setting Screen (Fig. 3).



(Fig. 3)

- 3) Press the "Number" key ③ and input a sound velocity ④ to appropriate the distance measurement.
- 4) After inputting above, press the V-set key ② to return the mode to the previous screen. (Fig. 2)
- 5) Touching the image in the screen displays the active point ⑤ in the touching position.
- 6) Use the point moving key (6) to micro-adjust the position of active points.
- 7) Press the Back key 7, so the active point will be deleted and replaced with one preceding active point.
- 8) Press the bar moving key ® to move the active bar 9 in the color scale.
- 9) Pressing the SW key ① changes over the active bar ②. The range of gradation values is also displayed in figures marked above the SW key ①.



(Fig. 4)

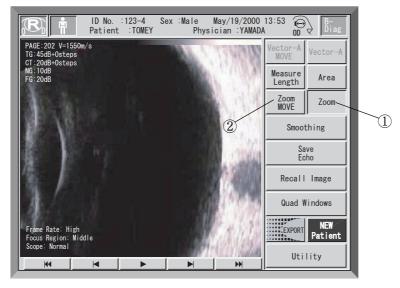
- 10) Press the Calculation key ②, so the beginning point and the ending point are connected to start area calculation. The letters of "Now Processing" are shown in the results display panel ③ in process of calculation. When the calculation is finished, the calculation results will be displayed. And the pixels corresponding to the gradation range in the enclosure is colored with a light blue. The pixel count ⑥ will be displayed below the calculation results. (Fig. 4)
- 11) Then press the Clear Inside key ①, so the calculation results will b deleted leaving lines.

Note ■ If any cursor position is once deleted, such position will not be restored. Therefore, sufficient confirmation shall be given before deleting the cursor position.

- 12) Press the Clear All key ® to delete all calculation results and lines.
- 13) Press the Area key (19) to return to the main screen. (Fig. 2) All the areas which have been set are deleted at the same time.

g) Zoom

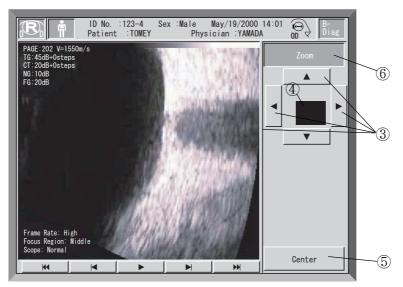
The image is magnified by 1.5 times with this function. This function, while it is being set, does not allow the use of the vector-A function (d) of this section). No magnification can also be given by the Quad image display function (k) of this section).



(Fig. 1)

<Switching actual size and magnified size>

Switching of actual size vice versa 1.5 times magnification can be made by pressing the Zoom key ①.



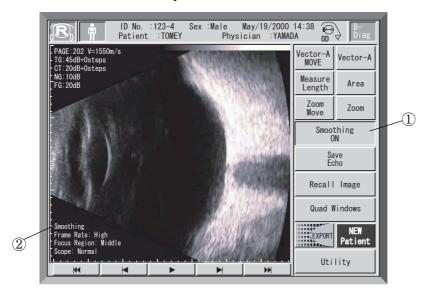
(Fig. 2)

<Movement of the magnification display range>

- 1) First press the Zoom MOVE key ② to change the mode for zoom positioning set screen. (Fig. 2)
- 2) Press the display range moving key ③, to move the display range. The display range movement key, if continuously pressed, keeps moving the display range and if pressed for short time, moves the display range to the neighboring area. The black square shape ④ in the middle of the quad display range moving keys simultaneously represents the magnification of a particular portion of the actual size display. If the display range is moved, its display will also be interlocked with such movement.
- 3) Press the Center key ⑤, so the magnification area will be moved to the center of the body.
- 4) Press the Zoom key ⑥ to return the mode to the main display with the magnification display as being left.

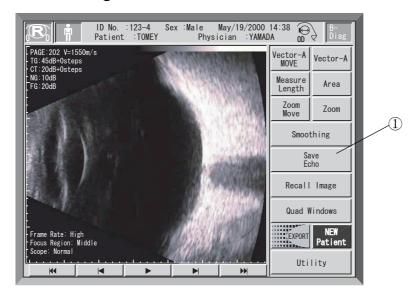
h) Smoothing

Smoothening is used to smoothen the connection of frames, to reduce irregularly occurring noises and to improve the quality of the images, which is, however, not suitable for viewing animated images accompanied by fast movement.



Press the Smoothing key ① to set the function. Every time when pressing this key, the setting mode is changed over alternately. While the smoothening function is being set, "Smoothening ②" is shown in the image.

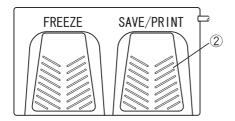
Echo Data Storage



You can store the image on screen as Echo Data Format onto memory card. Echo Data Format: This Format is originally designed for TOMEY Ultrasound B-Scan. The image, saved as this format, can be loaded and displayed by using Stored Data Display Function.



- Motes Make sure that Memory Card is inserted into main unit properly.
 - Patient ID and OD/OS must be properly selected, before storing the data into Memory Card.
 - DO NOT remove Memory Card, while the data is stored or loaded. Otherwise, all the data on Memory Card will be damaged.



- 1) Show the image, which should be stored on Memory Card
- 2) Press "Store Echo" ① or SAVE/PRINT on footswitch ② to store the displayed image on Memory Card. When using footswitch, one of "SAVE", "SAVE/PRINT", "SEND/SAVE" or "SEND/SAVE/PRINT" must be selected as footswitch settings. Please refer to "3.11.2.h) Footswitch Function Settings" for details.

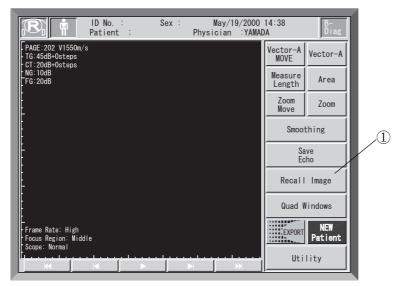
When storing the image on Memory Card, Patient ID, Patient Name, OD/OS, Sex, Physician's Name, Probe Angle, Time and Date, Total Gain, Contrast, Near Gain and Far Gain are simultaneously stored.

j) Stored Image Display

The image, stored on Memory Card as Echo Data Format, can be loaded by using this function. This function is not activated until any image is stored on Memory Card. The image, loaded from Memory Card, will be transformed to JPEG format. The JPEG images can be loaded or edited by importing into Personal Computers.

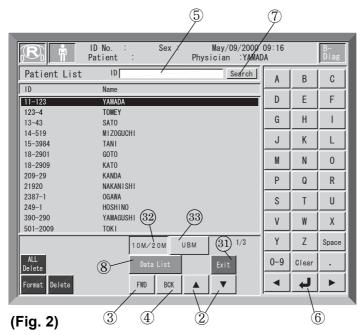


- DO NOT remove Memory Card, while the data is stored or loaded on screen. Otherwise, all the data on Memory Card will be damaged.
- DO NOT remove Memory Card, while the displayed image is loaded on screen from the same Card. Otherwise, the displayed image will be closed and the screen changes into Freeze Initial. (Fig.1)
 - 1) Insert the Memory Card. (Refer to 3.2.1 f) Insert/Remove Memory Card).

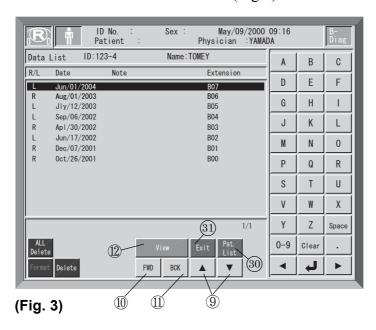


(Fig. 1)

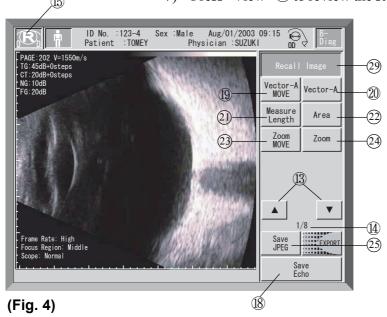
2) Press "Stored Image Display" ① to go to Patient List (Fig.2).



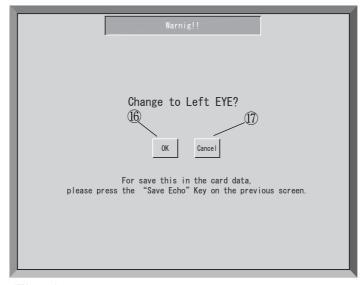
- 3) When "10M/20M" ③2 is selected, the images, captured by standard B-Scan probe (10MHz) or optional 20MHz anterior probe, are listed. When "UBM" ③3 is selected, the images by optional High Frequency Probe are listed.
- 4) Press "Up/Down" ②, "FWD" ③, "BCK" ④ to select the patient. You can search patient by Patient ID. Click on the blank ⑤ for ID type in and type ID for the patient you want to search. Click on the blank again or press "Enter" ⑥ to complete input. Then, press "Search" to list the patient you want to search. If the patient with typed ID is not on the list, the patient will not be listed on screen.
- 5) Press "Data List" ® to list the images of the selected patient (Fig. 3).



- 6) Press "Up/Down" (9), "FWD" (10), "BCK" (11) to select the data.
- 7) Press "View" ② to review the stored data (Fig.4).

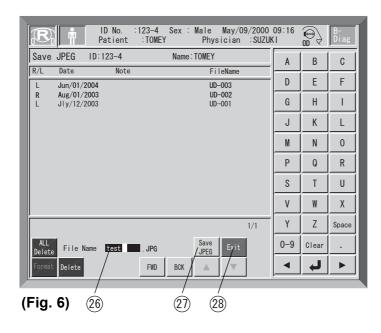


- 8) Press "Up/Down" (3) to page up/down the images on the list for selected patient. The image number and total amount of images are shown on screen (4).
- 9) Press "OD/OS" (5) to switch the eyes to be measured. Each time the button is pressed, warning screen (Fig. 5) comes up on screen.



(Fig. 5)

- 10) Press "OK" (6) on the screen to change from OD to OS or OS to OD and go back to former screen (Fig.4). The change on Memory Card will NOT be saved until "SAVE Echo" (18) is pressed.
- 11) Press "Cancel" ① on the screen to cancel OD/OS change and go back to former screen (Fig.4).
- 12) Press "SAVE Echo" ® to change save OD/OS on Memory Card.
- 13) Refer to d) Vector A Function for "Vector A Move" (19) and "Vector A" 20.
- 14) Refer to e) Measure Length for "Measure Length" (21).
- 15) Refer to f) Area for "Area" (22).
- 16) Refer to g) Zoom for "Zoom" (23).



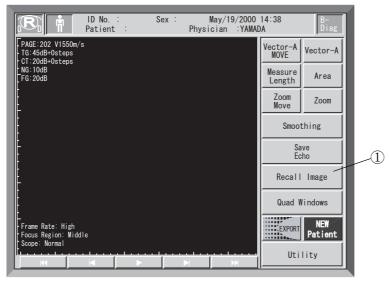
- 17) Press "Save JPEG" (25) to change screen to JPEG data list (Fig.6).
- 18) File Name can be typed in by using Key Pad. The name should be up to 8 characters. "." And " " (Space) cannot be used as a character.
- 19) Press "Save JPEG" (27) to start saving the image as JPEG. "Now Processing..." sign is on screen, while the unit is saving image on Memory Card. When the sign has gone, the saving process is completed and new data appears on the list.

- 20) Press "Exit" (28) to go back to Store Image Screen (Fig.4).
- 21) Press "Recall Image" ② to go back to Data list of a patient (Fig.3).
- 22) Press "Patient List" (30) to go back to Patient List (Fig.2).
- 23) Press "Exit" (31) to go back to Freeze Screen (Fig. 1).

<Delete Data on Memory Card>

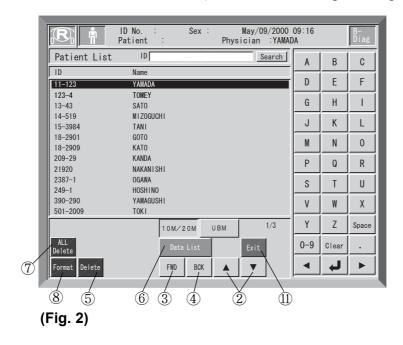
Note ■ The data, which was once deleted, cannot be restored.

Please pay special attention not to delete necessary information.



(Fig. 1)

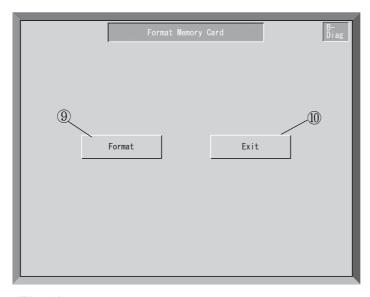
1) Press "Recall Image" ① to go to Patient List (Fig.2).



- 2) Press "Up/Down" ②, "FWD" ③, "BCK" ④ to select patient. Press and hold "Delete" (5) for one second to delete all the data for the patient.
- 3) When deleting a part of data for a patient, press "Data List" ⑥ to go to Data List screen and press "Delete" for one second to delete the data.
- 4) When deleting all data on the list, press "Delete All" (7) and keep holding for one second to delete all.

Note Once the Memory Card is formatted, all the data on the card will be lost. Lost data cannot be restored.

5) Press "Memory Card Format" (8) to go to the Format screen (Fig.3).

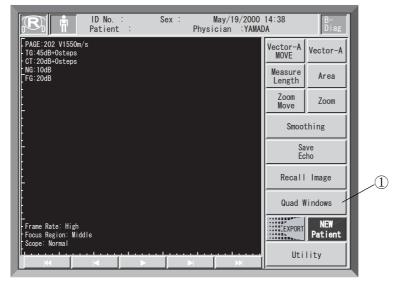


(Fig. 3)

- 6) Press "Format" (9) to format the card. While formatting, "Now Processing..." is displayed. When it is gone, format is completed.
- 7) Press "Exit" ① to go back to Patient List (Fig.2).
- 8) Press "Exit" ① again to go back to Main Screen (Fig.1).

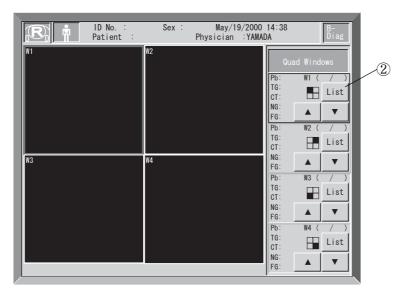
K) Quad Windows (Four Images Display)

Four images are simultaneously displayed on screen. The images must be saved on Memory Card as Echo Data Format, before using this function. JPEG images cannot be used on this function.



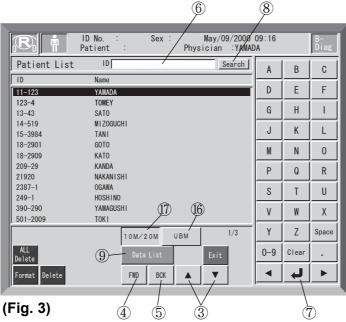
(Fig. 1)

1) Press "Quad Windows" ① to go to Quad Windows Mode (Fig.2).

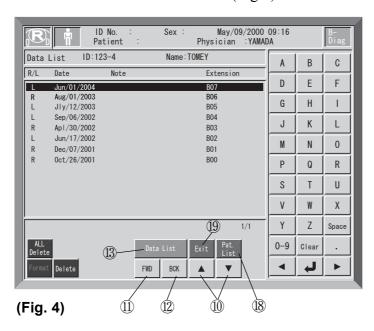


(Fig. 2)

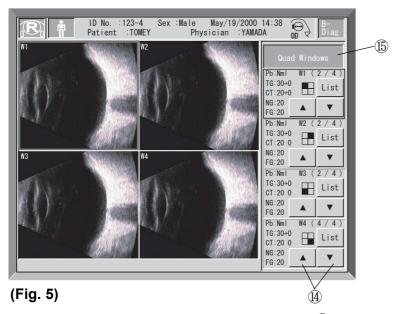
2) Press "List" ② to go to Patient List Screen (Fig. 3).



- 3) When "10M/20M" (6) is selected, the images, captured by standard B-Scan probe (10MHz) or optional 20MHz anterior probe, are listed. When "UBM" (7) is selected, the images by optional High Frequency Probe are listed.
- 4) Press "Up/Down" ③, "FWD" ④, "BCK" ⑤ to select the patient. You can search patient by Patient ID. Click on the blank ⑥ for ID type in and type ID for the patient you want to search. Click on the blank again or press "Enter" ⑦ to complete input. Then, press "Search" ⑧ to list the patient you want to search. If the patient with typed ID is not on the list, the patient will not be listed on screen.
- 5) Press "Data List" (9) to list the images of the selected patient (Fig. 4).



- 6) Press "Up/Down" ①, "FWD" ①, "BCK" ② to select the data.
- 7) Press "View" (3) to review the stored data (Fig. 5).
- 8) Press "Patient List" (18) to show Patient List Screen (Fig. 3).
- 9) Press "Exit" (19) to go back to Quad Windows Screen (Fig. 2).

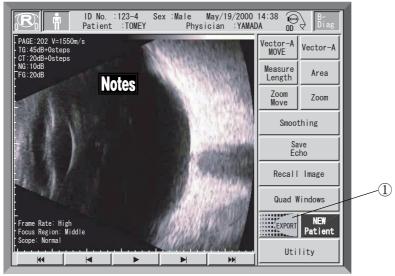


- 10) Press "Up/Down" (4) to page up/down the images on the list for selected patient.
- 11) When one out of four images is active (surrounded by frame in red), the screen shows OD/OS and Patient INDEX information for the active image. When selecting other image by touching it on screen, active image will be changed.
- 12) Press "Quad Windows" (5) to go back to main screen (Fig.1).

I) Transfer of patient data

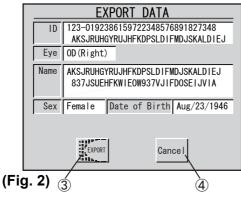


- Note For data communication with this instrument, "TOMEY Link", the networking available system (optional), or "DATA Transfer" (accompanying this instrument) is needed.
 - See each manual of TOMEY Link or DATA Transfer for their setting.
 - Connecting to TOMEY Link or DATA Transfer needs communication setting. See "3.8.2 f) Setting of data communication".
 - Without ID number data transfer may not be done depending on the setting. See "3.8.2 f) Setting of data communication".
 - Input of ID number for data transfer is recommended. Data can be transferred without ID number, but patient identification may not be possible in the test data output with DATA Transfer. When sending the data without ID number, confirm the data immediately after data transfer and move and store the data in an appropriate place. When connected to TOMEY Link, all the data without number are regarded as data of the same patient. Be careful not to make a mistake.

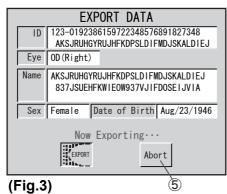


(Fig. 1)

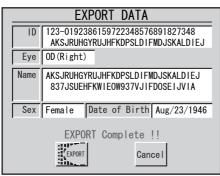
1) Press the EXPORT ① to change the screen mode to the EXPORT Confirmation screen (Fig. 2).



- 2) Patient ID, eye to be measured, patient's name, patient's gender, and patient's birthday are displayed in the EXPORT Confirmation screen (Fig. 2). Press the EXPORT key ③ to start communications.
- 3) If no communications is used, press the Cancel key ④, so no communications will be given and the screen will be returned to the initial screen.

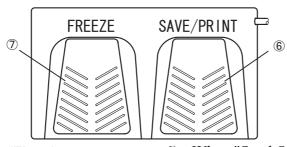


4) The message of "Now Exporting....." is displayed while in communications. (Fig. 3) When discontinuing communications, press the Abort key ⑤, so the communications will be suspended and the screen will be returned to the EXPORT Confirmation screen (Fig. 2).



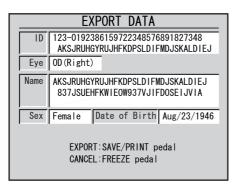
(Fig. 4)

5) When communications is properly finished, the message of "EX-PORT Complete" is displayed. (Fig. 4) In the event the error message is displayed, see "6. TROUBLESHOOTING".



(Fig. 5)

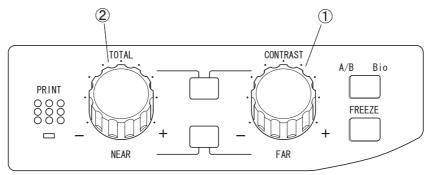
When "Send Only", "Send and Print", "Send and Store" or "Send/Store/Print" is selected in the footswitch function setting, data can be sent to TOMEY Link or to DATA Transfer by stepping the footswitch pedal "SAVE/PRINT" ⑥ just after freeze.



(Fig. 6)

When stepping the footswitch pedal "SAVE/PRINT" (6), the EXPORT confirmation screen will appear. Step "SAVE/ PRINT" pedal 6 for send and "PREEZE" pedal 7 for cancel. The screen will go back to the previous one automatically after sending the data.

m) Total gain vs. contrast change after freeze



This function changes the total gain and the contrast of the acquired images after freeze. The CONTRAST volume ① and the TOTAL volume ② are used for adjustment. The adjustable range is -6 to +6 (steps) and the total gain is -5 to +5 (step). This value is not of decibels. (dB).

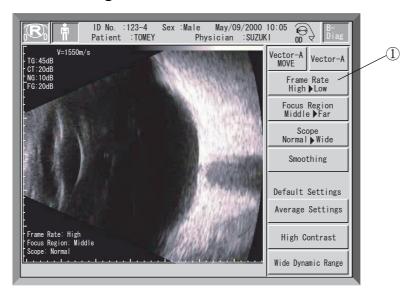
This function is used when moving picture playback and for setting-up of the functions of vector-A, distance measurement, area calculation, zoom, smoothing, saved image display, and quad images display.

3.3.9 Various functions at real time

a) Vector-A

See "3.3.8 d Vector-A function".

b) Frame rate setting

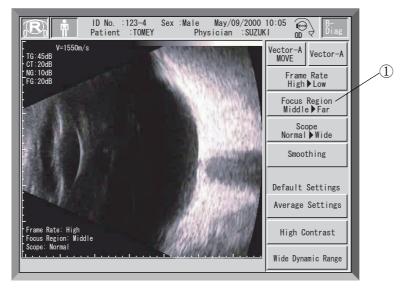


This function sets the frame rate in two steps. "High (22 frames/sec.)" allows smooth and natural moving images even in case of fast moving testing eye and still short playback time for one travel of moving image playback function, while "Low (11 frames/second) does the inferior smoothness than "High" in the movement of images by taking a twice longer time of moving picture playback than that for "High".

Setting of this function is made by pressing the Frame Rate key ①. Each press of this key changes the setting of "High" vs. "Low" alternately.

c) Focus regions setting

This function sets three focus regions depending on the observation position.



Press the Focus Region key ① for this setting. Each pres of this key changes over three stages of "Near", "Middle" and "Far".

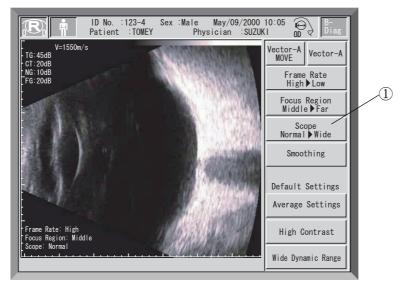
<Focus regions>

The following shows three focus regions from the head of the probe for setting of the scope function (explained in subparagraph below).

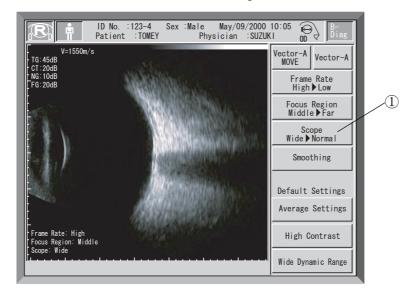
• Near	■ Normal	: approximately 11 to 19mm
	■ Wide	: approximately 13 to 21mm
Middle	■ Normal	: approximately 16 to 24mm
	■ Wide	: approximately 18 to 26mm
• Far	■ Normal	: approximately 21 to 29mm
	■ Wide	: approximately 23 to 31mm

d) Scope

This function sets the scope of display depth of the image in two steps. Therefore, select the scope to suit the region desired for observation.



Press the Scope key ① for this setting. Each press of this key sets the scope for "Normal" and "Wide" alternately.

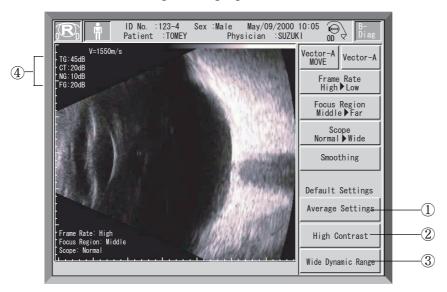


e) Smoothing

See "3.3.8 h) Smoothing".

f) Presetting of each gain and contrast

Three groups of presetting values for total gain, contrast, near gain and far gain are prepared for this instrument



<Average Settings ①>

Total gain, contrast, near gain and far gain are set with the standard values.

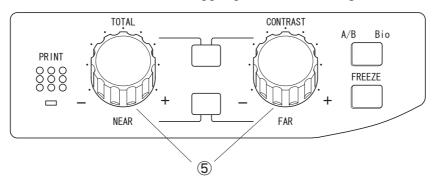
<High Contrast ②>

The images are displayed with clear definitions, provided that, due to its low gradation, it is not convenient for observation of delicate changes in the organization of the eye. It is most conveniently used for observation of the retina.

< Wide Dynamic Range 3>

Its high gradation and wide dynamic range are effective for observation of delicate changes in the organization, except for that unnecessary echo and arch fact (such as imaginary images which are caused by the reflection and/or refraction of ultrasound beams). It is, therefore, suitable for observation of the opacity and bleeding in the inside of the vitreous body.

1) Press any key of the Average Settings key ①, the High Contrast key ②, and the Wide Dynamic Range key ③ to set total gain, contrast, near gain, and far gain at the values to suit the selected keys. Each set value is displayed at the left upper part ④ of the image.



2) Turn the volume ⑤ for adjustment. If set value is changed, the selecting condition will be released.

3.4 Assistant function of Biometry

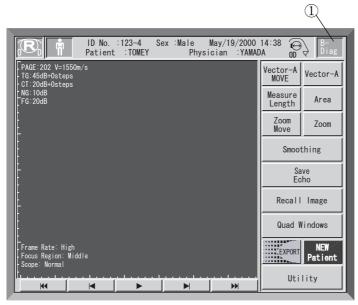


This function is an additional function used for biometry purpose, but it is not a biometry instrument.

This function is intended to provide information to determine the data to be employed for measurement, by using the B-scan image, in case no stable biometry results are obtainable with the ordinary biometry instrument due to intraocular disease.

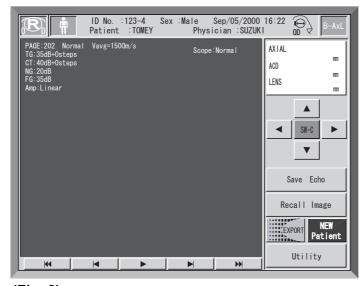
This function which provides amplifying characteristics similar to those for biometry detects the anterior of the cornea on the line displayed in the ultrasound image, in an approximate position of the anterior of the crystalline lens and that of the retina, to display the cursors in the detecting position on the line (x-mark: cornea anterior cursor, crystalline lens anterior cursor, and retinal cursor). The mentioned line and each cursor are movable, while the cursor moves right and left on the line. And this function displays the distance between the corneal anterior cursor and the retinal cursor and that between the corneal anterior cursor and the crystalline lens anterior cursor. The examiner moves the lines and the cursors to his/her favorable position, by referring to detected positions.

3.4.1 Changing to the biometry assistant (sub-) function



(Fig. 1)

When the power source of the instrument is turned on, the operation starts with the B-scan image diagnosis function. Next press the B-Diag key ① in the Freeze screen (Fig. 1) for approximately one second, so the instrument will automatically adjust the B-scan probe as well as itself.

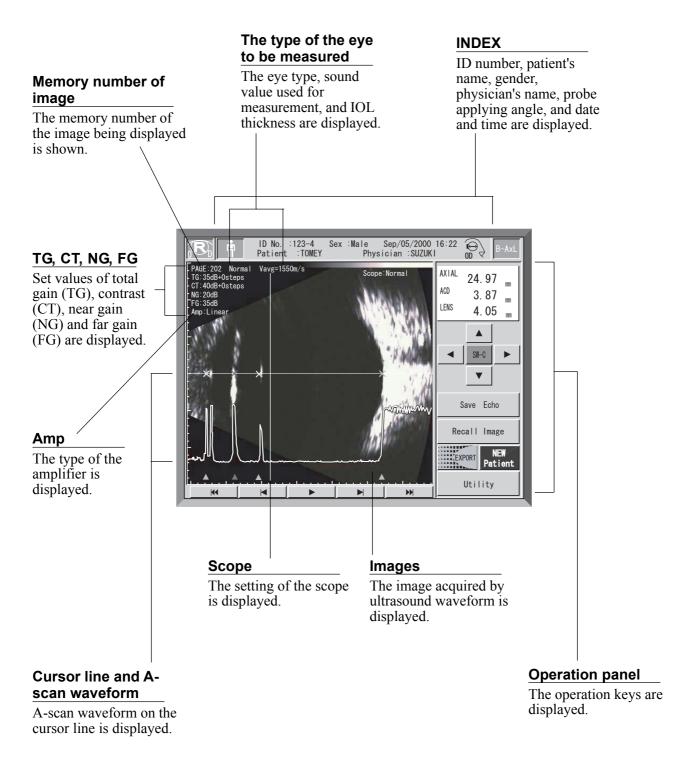


(Fig. 2)

If the error message is displayed, take appropriate countermeasures by referring to "6. TROUBLESHOOTING". When the above adjustment has properly been completed, the screen will show the Biometry Subfunction (Fig. 2).

3.4.2 Screen display information

a) Diagnosis display



b) Main menu at freeze

select **Estimated ACD display** The function is The distance from the surface of changed to the Athe cornea to that of the lens is scan diagnosis mode. Index displayed as an estimated ACD. The screen mode is changed to the Index **Estimated LENS display** Input screen. **Estimated Axial Length** The distance from the surface The distance from the surface of the lens to the bottom of of the cornea to the retina is the lens is displayed as an displayed as an estimated estimated LENS. Setting of the eye Axial length. to be measured The eye to be examined is set for either of right or left. ID No. :123-4 Sex :Male Sep/05/2000 Patient :TOMEY Physician :SUZUKI Save Main 24. 97 The image being 3.87 displayed and the 4.05 patient data are saved **Cursor line move** in the Echo format into the memory The cursor line is card. moved. **Recall Image** The screen is Recall Image changed to the Saved Image Display EXPORT Patient screen. Utility Move cursor key The key moves the cornea Moving image front cursor, the lens front playback key cursor, and the retina Captured image is cursor. played back. **NEW Patient EXPORT TOMEY Link** All the patient data and Utility The screen is changed to measured data are deleted and The screen is the EXPORT Confirmation measurement is prepared for changed to the Utility the new patient. screen. screen.

SW-C key

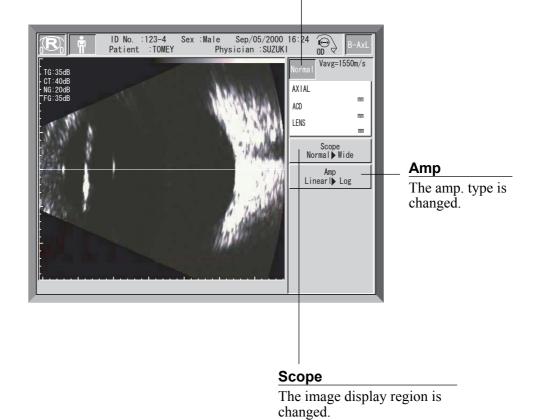
The key changes the cursor to the moving cursor (active cursor).

Diagnosis mode

c) Main menu at scanning

The type of eye to be measured

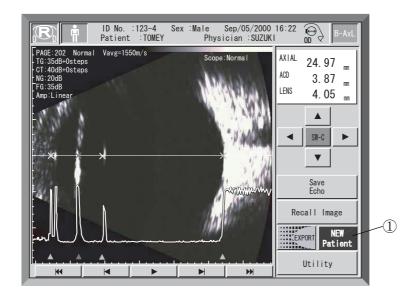
The type of eye to be measured, the ultrasound velocity, and the IOL thickness are set.



3.4.3 Deletion of all measured data (Measuring preparation for new patient)



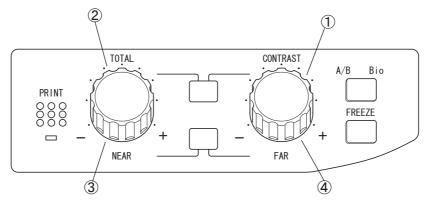
- Since data, if once deleted, cannot be restored, sufficient check shall be given before deleting data.
- Be sure to press the NEW Patient key to delete all saved patient data, before the new patient is placed for measurement. If data for next patient is taken without pressing NEW Patient key, patient information and acquired data will not possibly be corresponding.



Pressing of the NEW Patient key ① for approximately one second until the "beep" sound is made deletes patient information (ID, patient's name, and gender), the eye measured (R/L), image data, and measurement results and then displays the new diagnosis screen. The eye to be examined is set as unspecified.

3.4.4 Setting of various gain volumes

Fine adjustment of various gain volumes shall be given by observing ultrasound images and A-scan waveforms.



a) CONTRAST volume ①

The contrast (or the difference between white and black) of the image is set. (Adjustable range: 1 to 60dB)

b) TOTAL volume 2

The echo sensitivity of the whole images is set. (Adjustable range: 1 to 60dB)

c) NEAR volume ③

The reflective echo in the area near the anterior is set. (Adjustable range: 1 to 40dB)

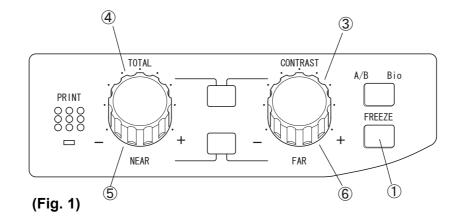
d) FAR volume 4

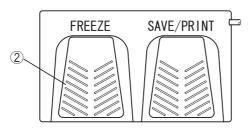
The reflective echo sensitivity in the area near the retina and the anterior chamber is set. (Adjustable range: 1 to 40dB)

3.4.5 Entering of Index data

See "3.3.4 Entering of Index data".

3.4.6 Acquisition of ultrasound images





(Fig. 2)

Note ■ Patient's cooperation is helpful for successful examination. Therefore, sufficiently explain about the examination procedure to the patient before giving examination. The patient should have a relaxed feeling during examination.

- 1) Have the patient lay down himself.
- 2) In case of freeze condition, press the FREEZE button ① or the footswitch pedal ② to release the condition of "freeze".
- 3) Put the attachment to the head of the B-san probe and next fill the attachment with ultrasound gel without letting air bubbles insides.
- 4) Directly apply the upper part of the attachment to the eyelid to be examined.
- 5) Adjust each gain volume of CONTRAST ③, TOTAL ④, NEAR ⑤, and FAR ⑥ so that the images and A-scan waveforms can be obtained in their optimum condition.
- 6) For taking the images in, press the FREEZE button ① or press the footswitch to make the "freeze" condition.

3.4.7 Various functions at freeze

a) Moving images playback

See "3.3.8 a) Moving images playback".

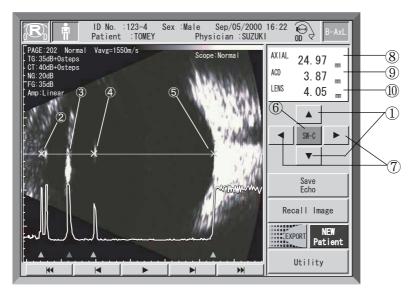
b) Frame (page by page) forward/backward display function

See "3.3.8 b) Frame (page by page) forward/backward display

c) Skip display

See "3.3.8 c) Skip display ".

d) Movement of the cursor line and each cursor



- 1) Press the cursor line moving key (UP/DOWN) ①, so the cursor line will move up and down. Move the cursor line, so each of the cornea front cursor ②, the crystalline lens front cursor ③, the crystalline lens rear cursor ④, and the retina cursor will automatically move to its automatically detected position. If, however, not automatically detects, the cursor will not be displayed. The moving range of the cursor line is $\pm 10^{\circ}$ from the center axis of the probe.
- 2) Press the SW-C key 6, so the movable cursor (red: active cursor) will be changed to the other mode.
- 3) Press the cursor moving key (left/right) 7, so the active cursor will move left and right over the cursor line.
- 4) The screen then shows the distance ® between the cornea front cursor and the retinal cursor and that (9) between the cornea front cursor and the crystalline lens front cursor. As for setting of the sound velocity, see "3.4.8 a) Eye type setting function".

e) Echo data saving

As for the operating procedure, see "3.3.8 i) Echo data save function" of the B-scan image diagnosis function. The saving data include set values of images, ID number, patient's name, the eye to be examined, patient's gender, physician's name, probe applying angle, data and time, measuring results, each cursor and cursor line position, contrast (CT), total gain (TG), near gain (NG), and far gain (FG).

JPEG image saving

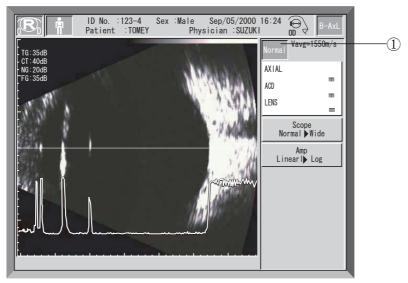
See "3.3.8 j) JPEG image saving".

g) Transfer of patient data

See "3.3.81) Transfer of patient data".

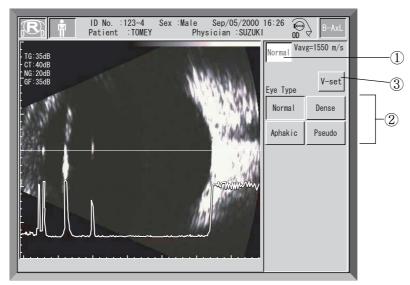
3.4.8 Various functions at real time

a) Setting of eye type to be measured



(Fig. 1)

1) Press the eye type setting key ①, the screen mode will be changed to the Eye Type Setting screen (Fig. 2).

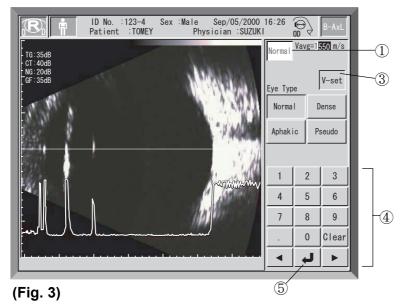


(Fig. 2)

- 2) Select the eye type in the Eye Type Select screen 2.
- 3) Press the Eye Type Setting key ① to return the screen mode to the initial screen (Fig. 1).

<Setting of sound velocity>

1) After selecting desired the eye type in the Eye Type Setting screen (Fig. 2), press the Sound Velocity Setting key ③ to change the screen mode to the Sound Velocity Setting screen (Fig. 3).



2) Next press the Number key ④ to change the sound velocity and the lens thickness used for measurement. In case a multiple number of items are set, press the Enter key ⑤ to change to the following input items.

[Input ranges]

■ Normal

Biometry average ultrasound velocity: 1,500m/s to 1,600m/s

■ Dense

Biometry average ultrasound velocity: 1,500m/s to 1,600m/s

■ Aphakic

Biometry average ultrasound velocity: 1,430m/s to 1,630m/s

■ Pseudophakic

Biological ultrasound velocity: 1,000m/s to 2,000m/s IOL ultrasound velocity: 800m/s to 3,000m/s IOL thickness: 0.10mm to 4.00mm

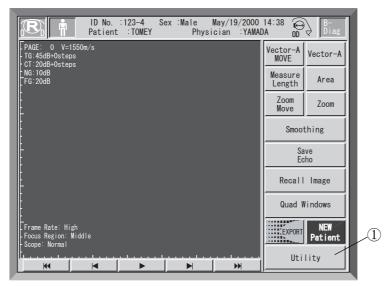
3) After finishing the setting screen, press the Ultrasound Velocity Setting key ③ and the Eye Type Setting key ① in order, to return the screen mode to the preceding screen (Fig. 1).

b) Scope

See "3.3.9 d) Scope".

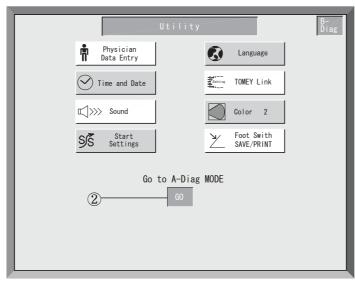
3.5 A-scan Diagnosis

3.5.1 Changing to the A-scan diagnosis function



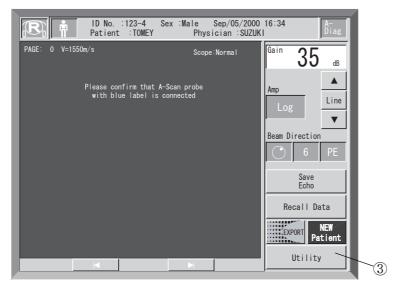
(Fig. 1)

1) When turning the power on, the instrument starts its operation from the B-scan image diagnosis function. Next press the Utility key ① in the Freeze screen (Fig. 1) of the B-scan image diagnosis function to change the screen mode to the Utility screen (Fig. 2). Then press the Utility key ① in the Freeze screen (Fig. 1) for B-scan image diagnosis function to change the screen mode to the Utility screen (Fig. 2), which can also be made from the Utility screen in the biometry measuring sub-function.



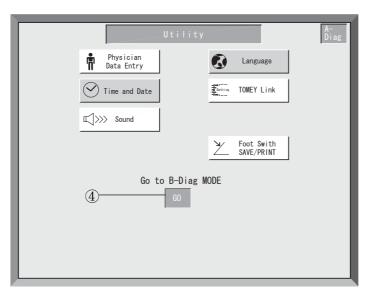
(Fig. 2)

2) After pressing the A-Diag select key ② for approximately one second, the operation mode will be changed to the Ascan diagnosis function. (Fig. 3)



(Fig. 3)

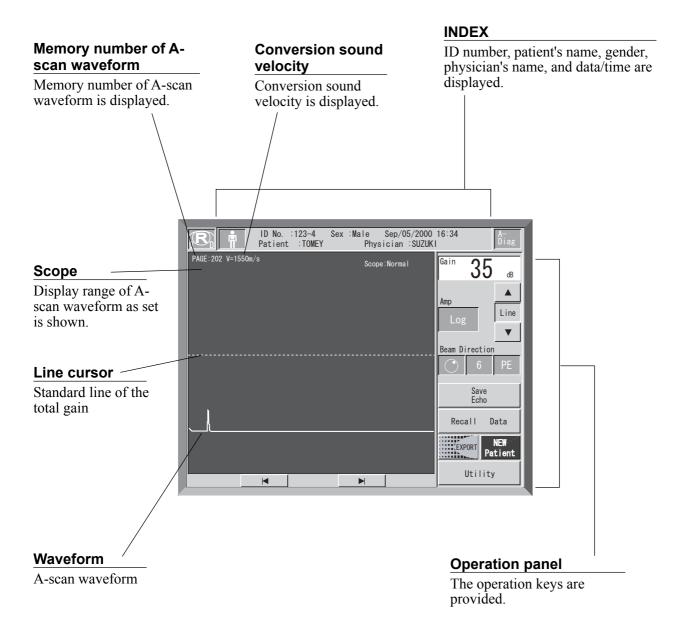
3) To return the A-scan diagnosis function to the B-scan diagnosis function or the biometry measuring sub-function, press the Utility key 3 to select the Utility screen (Fig. 4) and next press the B-Diag select key 4 for approximately one second to that the function will return to the B-scan diagnosis function. (Fig. 1)



(Fig. 4)

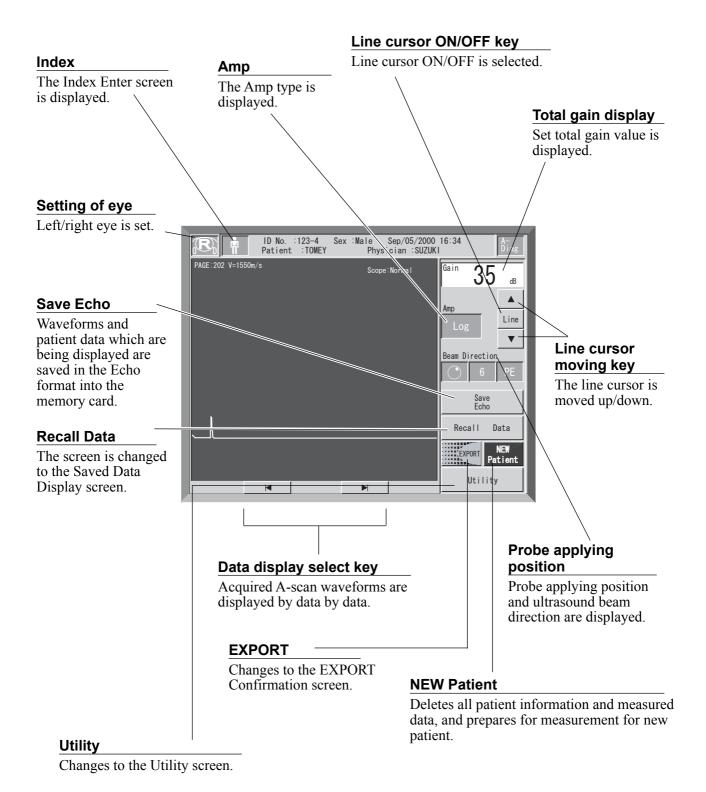
3.5.2 Screen display in formation

a) Diagnosis screen

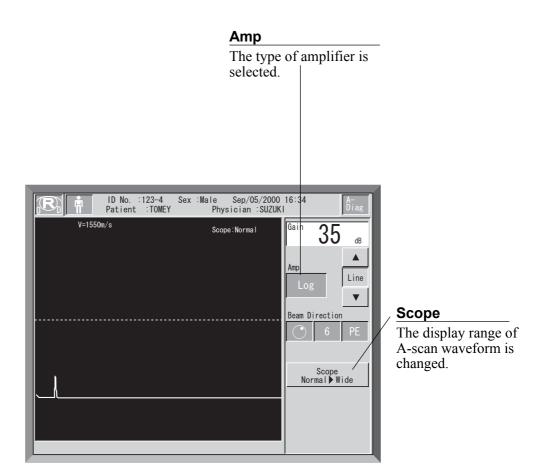


b) Main menu at freeze

Note ■ If the B-scan image diagnosis function is selected, all the data acquired by A-scan diagnosis function will be deleted.



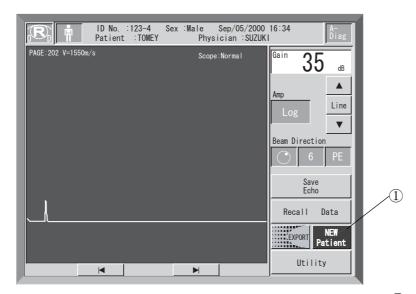
c) Main menu at real time



3.5.3 Deletion of all measurement data (Measuring preparation for new patient)



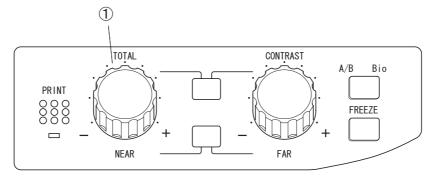
- No data, if once deleted, can be restored. Therefore, sufficient care must be taken for deleting data.
- Before examining a new patient, always press the NEW Patient key to delete all the data for the previous patient. If taking data the new patient without pressing the NEW Patient key, acquired data do not correspond to the patient information.



By pressing the NEW Patient key ① for approximately on second until the "beep" sound is made, patient information (ID, patient's name, and gender), the eye (R/L) to be examined, and waveforms are deleted and the diagnosis screen for new examination will be displayed. And the eye to be examined is set to be undesignated at the same time as this moment.

3.5.4 Setting of gain volume

Adjust the gain volume as watching the A-scan waveforms.



a) TOTAL volume ①

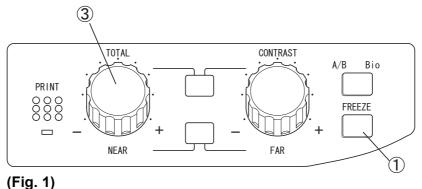
The echo sensitivity of the whole A-scan waveforms is set. (Adjustable range: 1 to 60dB)

3.5.5 Entering of index data

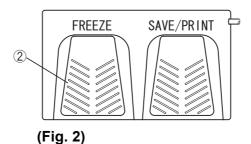
See "3.3.4 Entering of index data".

3.5.6 Acquiring of A-scan shape

Note Patient's cooperation is necessary for successful examination. Sufficient explanation should be given to the patient before carrying out examination. And have the patient relaxed during examination.



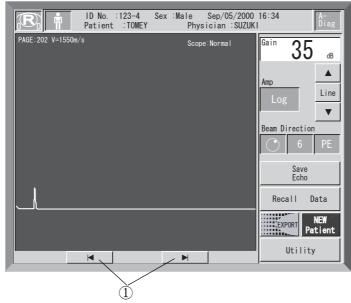
(Fig. 1)



- 1) If the operation is in the freeze condition, press the FREEZE button ① or the FREEZE pedal ② of the footswitch to release the freeze condition.
- 2) Apply an appropriate amount of the corneal protective gel to the eye to which the A-probe have contact.
- 3) Touch the A-scan probe to the eye to be examined.
- 4) Adjust the total gain ③.
- 5) When taking A-scan waveforms, press the FREEZE button or the FREEZE pedal ② of the footswitch to make a freeze condition.

3.5.7 Various functions at freeze

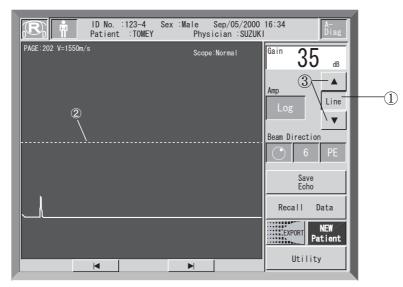
a) Data display change



This instrument memorizes as much capacity as for that of maximum 202 data. Acquired wave data are displayed in order, every time when pressing the Data Display Select key ①.

b) ON/OFF and movement of the line cursor

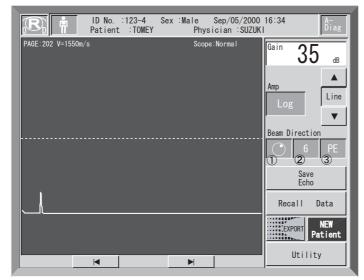
This line cursor can be used as the reference line of total gain.



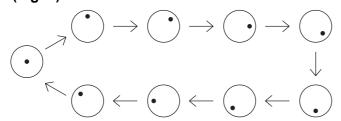
- 1) ON/OFF of the line cursor is alternately displayed every time when pressing the line cursor ON/OFF key ①.
- 2) If pressing the Line Cursor Move key ③ with the line cursor as being displayed, the line cursor is moved up and down.

c) Probe applying position and ultrasound beam direction display

This function is used to display the probe applying position, ultrasound beam direction, position of interest (lesion).

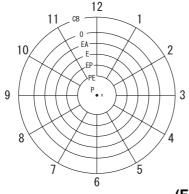


(Fig. 1)

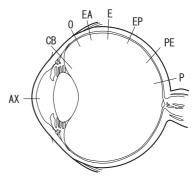


(Fig. 2)

- 1) Nine positions are each displayed every time when pressing the probe applying position key ①. (Fig. 2)
- 2) One to twelve directions are shown every time when pressing the beam direction key ②, which is useful to show the angle of the meridians. (Fig. 3)
- 3) The directions of $AX \rightarrow P \rightarrow PE \rightarrow EP \rightarrow EA \rightarrow O \rightarrow CB$ are alternately shown in this order every time when pressing the beam direction indicating key 2 ③, which is useful to show the portion of interest inside the eye while being examined. (Fig. 4)



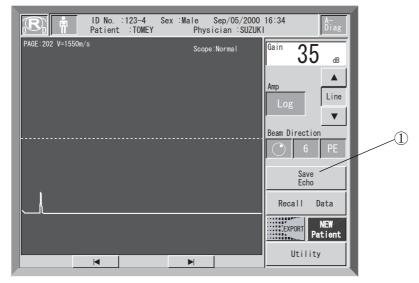
(Fig. 3)



(Fig. 4)

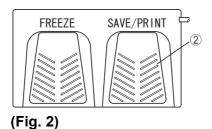
d) Data saving

This function is used to save acquired A-scan waveforms in the memory card.



(Fig. 1)

- Make sure that Memory Card is inserted into main unit properly.
 - Patient ID and OD/OS must be properly selected, before storing the data into Memory Card.
 - DO NOT remove Memory Card, while the data is stored or loaded. Otherwise, all the data on Memory Card will be damaged.

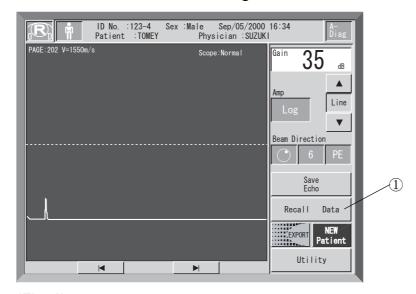


- 1) Waveforms to be saved are displayed in the freeze screen.
- 2) Data while being displayed in the screen is saved by pressing the Save Echo key ① or the SAVE/PRINT pedal ② of the footswitch. It is also noted that, for saving data by using the footswitch the footswitch must have been set at "SAVE", "SAVE PRINT", "SEND / SAVE" or "SEND / SAVE / PRINT". See "3.11.3 Setting of the footswitch".

e) Stored Image Display

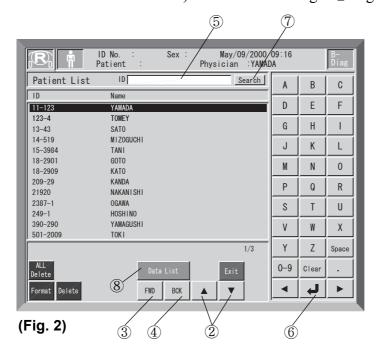
Note DO NOT remove Memory Card, while the displayed image is loaded from the same Card. Otherwise, the displayed image will be closed and the screen changes into Freeze Initial.

> This function is to display A Diagnostic waveform, saved on Memory Card. The A Diagnostic waveform should be saved on Memory Card, before using this function. Please refer to "d) Data Storage".

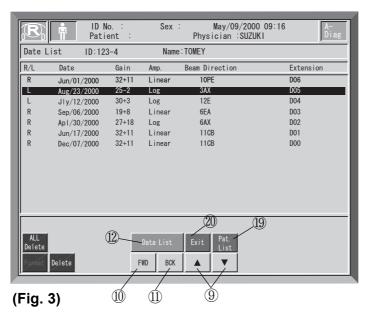


(Fig. 1)

Press "Recall Image" ① to go to Patient List (Fig.2).

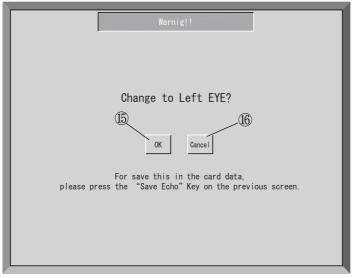


- 2) Press "Up/Down" ②, "FWD" ③, "BCK" ④ to select the patient. You can search patient by Patient ID. Click on the blank ⑤ for ID type in and type ID for the patient you want to search. Click on the blank again or press "Enter" (6) to complete input. Then, press "Search" ① to list the patient you want to search. If the patient with typed ID is not on the list, the patient will not be listed on screen.
- 3) Press "Data List" (8) to list the images of the selected patient (Fig.3).



- Press "Up/Down" (9), "FWD" (10), "BCK" (11) to select the data.
- Press "View" ② to review the stored data (Fig.4). le Sep/05/2000 16:35 Physician :SUZUKI ID No. Patient :123-4 :TOMEY Scope:Norma (13) Delete (Fig. 4)

- 6) Press "Up/Down" (13) to page up/down the images on the list for selected patient. The image number and total amount of images are shown on screen.
- 7) Press "OD/OS" (4) to switch the eyes to be measured. Each time the button is pressed, warning screen (Fig.5) comes up on screen.

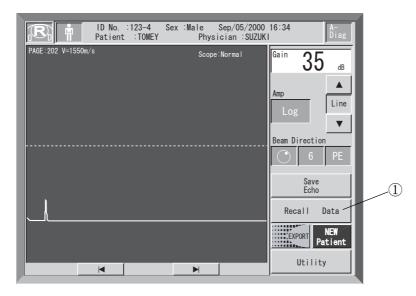


(Fig. 5)

- 8) Press "OK" ⑤ to change from OD to OS or OS to OD and go back to former screen (Fig.4). The change on Memory Card will NOT be saved until "SAVE Echo" ① is pressed.
- 9) Press "Cancel" (6) to cancel OD/OS change and go back to former screen (Fig.4).
- 10) Press "SAVE Echo" 17 to save change.
- 11) Press "Recall Image" ® to go back to Data list of a patient (Fig.3).
- 12) Press "Patient List" (19) to go back to Patient List (Fig.2).
- 13) Press "Exit" ② to go back to Freeze Screen (Fig. 1).

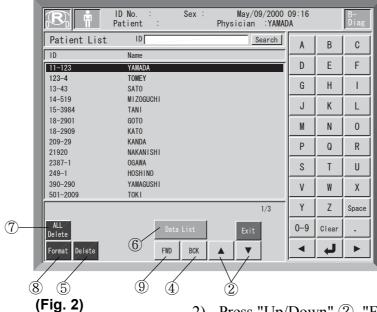
<Delete Data on Memory Card>

Note ■ The data, which was once deleted, cannot be restored. Please pay special attention not to delete necessary information.



(Fig. 1)

Press "Recall Image" ① to go to Patient List (Fig.2).

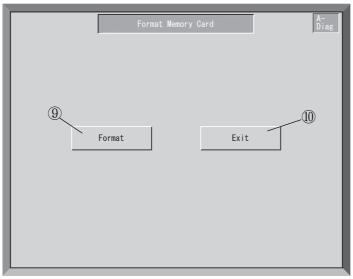


- Press "Up/Down" 2, "FWD" 3, "BCK" 4 to select patient. Press and hold "Delete" 5 for one second to delete all the data for the patient.
- 3) When deleting a part of data for a patient, press "Data List" ⑥ to go to Data List screen and press "Delete" for one second to delete the data.

4) When deleting all data on the list, press "Delete All" ⑦ and keep holding for one second to delete all.

Note Once the Memory Card is formatted, all the data on the card will be lost. Lost data cannot be restored.

5) Press "Memory Card Format" ® to go to the Format screen (Fig.3).



(Fig. 3)

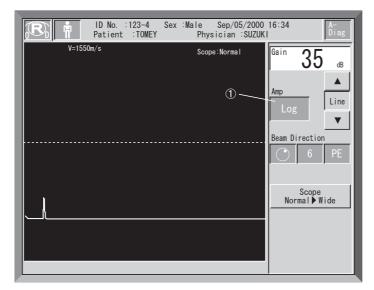
- 6) Press "Format" ⁽⁹⁾ to format the card. While formatting, "Now Processing..." is displayed. When it is gone, format is completed.
- 7) Press "Exit" ① to go back to Patient List (Fig.2).
- 8) Press "Exit" (1) again to go back to Main Screen (Fig. 1).

f) Transfer of Patient Data

Please refer to "3.3.8 l) Transfer of Patient Data" for more information.

3.5.8 Various functions at real time

a) Amp. selection



Log amp (Log), linear amp. (Linear), and S-curve amp (S) are alternately selected every time when pressing the Amp. Select key ①.

b) ON/OFF and movement of the line cursor

See "3.5.7 b) ON/OFF and movements of line cursor".

c) Probe applying position and ultrasound beam direction display

See "3.5.7 c) Probe applying position and ultrasound beam direction display".

d) Scope

See "3.3.9 d) Scope".

3.6 Biometry

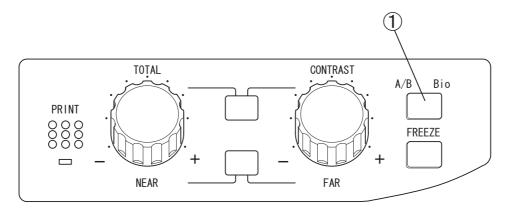
3.6.1 Turning the power on and adjustments

a) Turning the power on and adjustments

See "3.3.1 a) Turning the power on and adjustments".

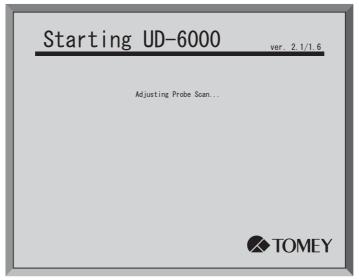
b) Switching to the biometry function.

When the biometry function is switched, all the data acquired by B-scan image diagnosis, the assistant function of biometry, and A-scan diagnosis function are deleted. Therefore, sufficient care is to be given before switching the biometry function.



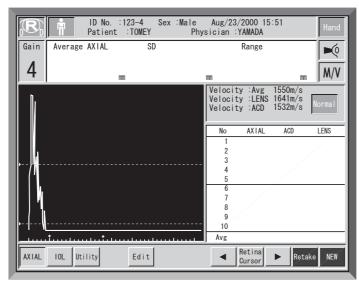
Press the A/B-Bio select button ① for longer than 3 seconds, so the biometry function will be turned on. This selection cannot be made at real time, in process of accessing to the memory card or while in LAN communication.

c) Starting screen display information



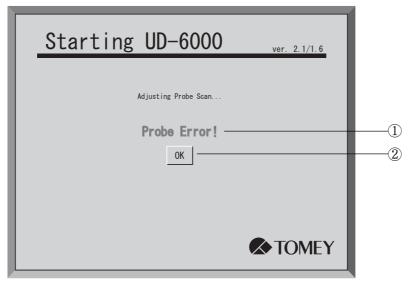
(Fig. 1)

1) Immediately after the power is turned on, the Start screen is displayed to calibrate the biometry probe. (Fig. 1)



(Fig. 2)

2) After the calibration of the probe is given properly, the Measurement screen (the initial screen) is displayed. (Fig. 2)



(Fig. 3)

3) If the calibration of the probe is not given, the message of "Probe Error" ① and the OK key ② will be displayed. (Fig. 3) If the OK key ② is next pressed, the Measurement screen (the initial screen) will be displayed. (Fig. 2) If the error message is displayed, see "6. TROUBLESHOOTING". If this error message is repeatedly displayed, consult with your Tomey representative from which you purchased your instrument.

3.6.2 Screen display information

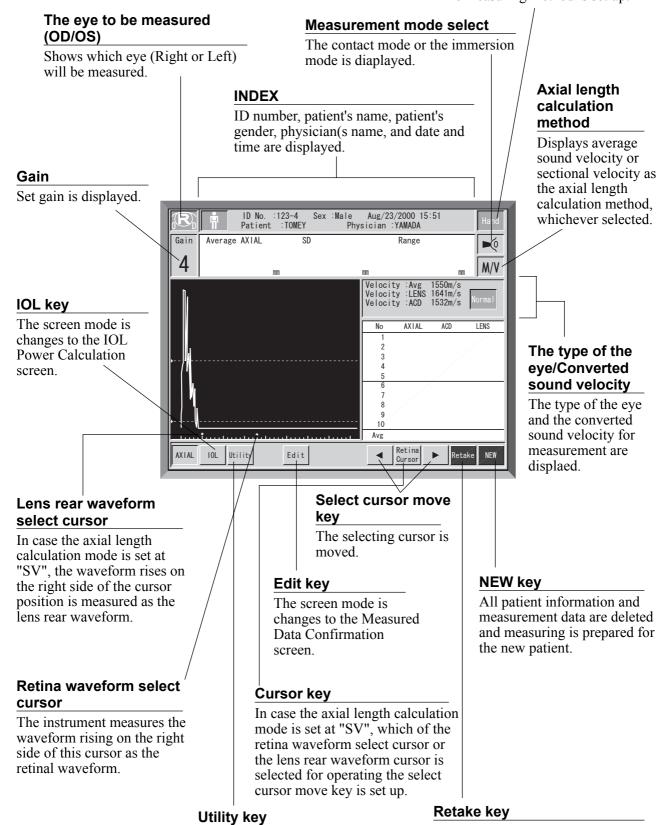
a) Measuring display

Measurement mode setup

The measuring method is set up.

Deletes measured data being

displayed and retakes data.



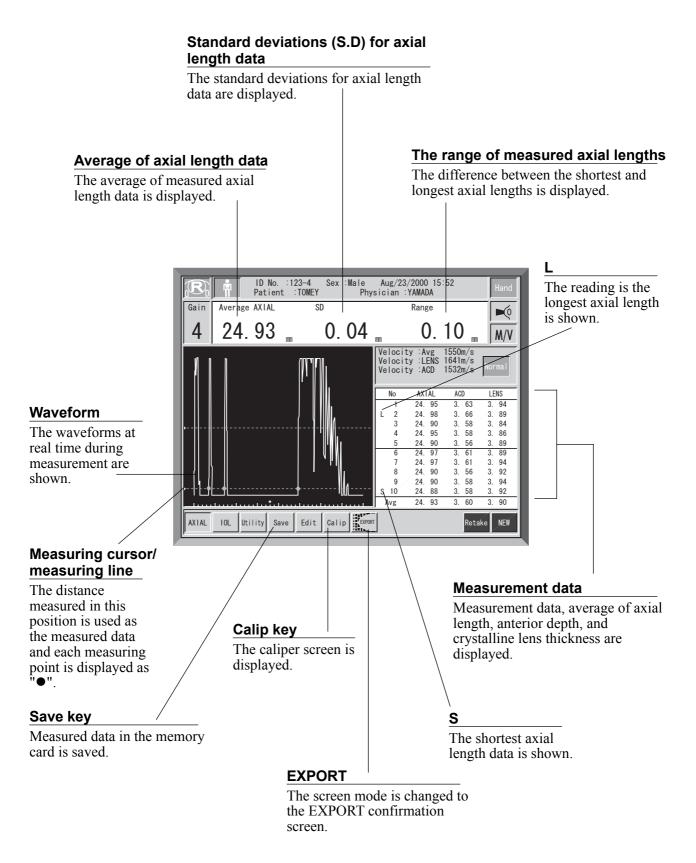
3-90

3.6 Biometry

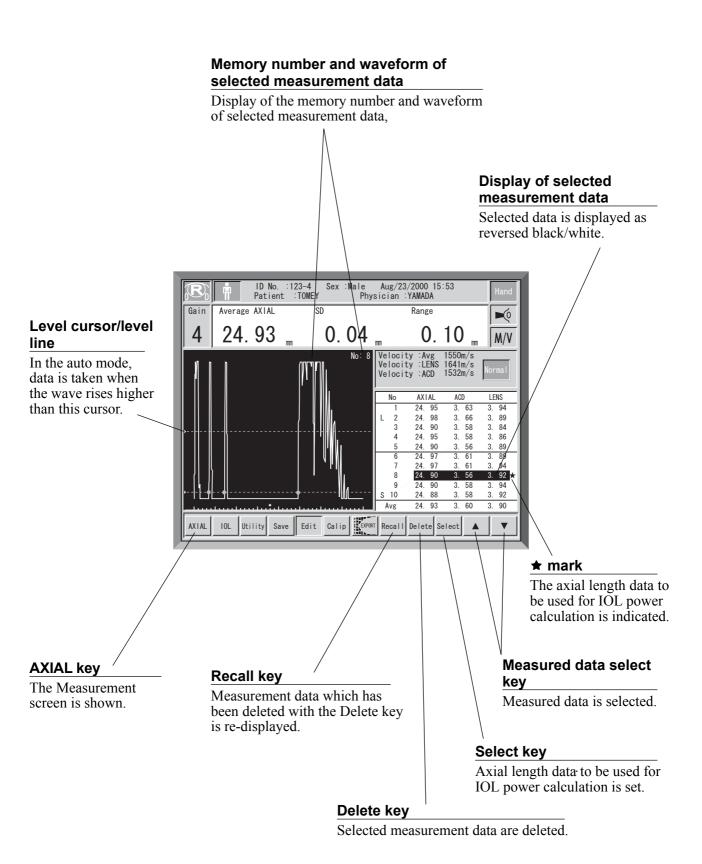
The Utility screen is

displayed.

b) Measuring finish screen



c) Confirmation display of measured data



3.6.3 Setting of measuring conditions

The following conditions are set immediately after turning the power on and after switching the function to the biometry mode.

· Eye to be measured: Right eye (R)

· Type of eye to be measured:

Normal (Sound velocity to be same

as set in the previous use.)

Measuring method: Same as that in the previous use
Gain: Same as that in the previous use
Measuring mode: Same as that set in the previous use

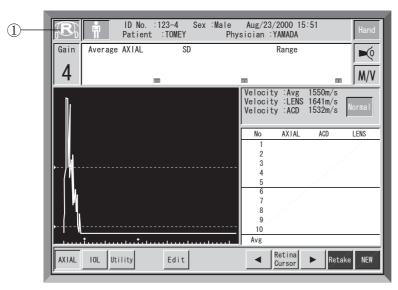
· Axial length calculation method:

Same as that set for the previous use.

■ For measuring the new patient, be sure to delete all previous patient data before pressing the NEW key before carrying out measurement for the new patient (See "3.6.9 a) Deleting of measurement data for both eyes (Measuring preparation for the new patient)". If taking measurement without pressing the NEW key, measured data may otherwise be mixed with data for previous patient.

a) Setting of the eye to be measured

Note



The right eye and the left eye are alternately displayed every time when pressing the Right/Left key ①. The biometry function and the IOL power calculation function (See "3.7 IOL power calculation".) acquire and save measured data for the right and left eye respectively. Accordingly, be sure to set the conditions for the eye to be measured before calculation.

b) Setting of the eye type to be measured and the sound velocity for conversion

Note ■ This function will be applied only on selected eye to be measured (OD or OS). The setting for both eyes cannot be changed automatically. The setting for each eye should be properly selected, according to the conditions.

> Select the eye type to be measured from the following four types for the eye to be measured.

■ Normal

Select "Normal" for the eye of which lens nucleus is relatively soft like an incipient cataract.

■ Dense cataract

Select "Dense cataract" if the lens nucleus of the eye to be measured is relatively hard like an overheated cataract and in case its measurement is difficult with "Normal" due to the reflective echo caused at the rear side of the crystalline lens.

■ Aphakic

Select "Aphakic" if the eye to be measured is an aphakic eye.

■ Pseudophakic

Select "Pseudophakic" if the eye to be measured is an IOL implanted eye.

In case of "Aphakic", no measurement of ""LENS" can be obtained for "ACD", "LENS", and "Pseudophakic".

In case of "Dense Cataract", there is a case that the instrument cannot detect the lens posterior wave due to multiple echoes generated in the lens.

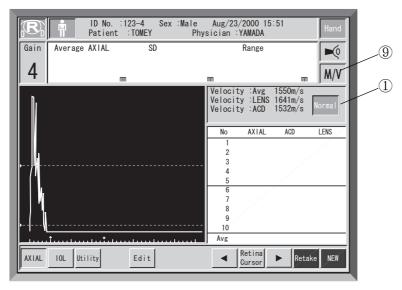
Eye Type	AXIAL	ACD	LENS
Normal	0	0	0
Dense	0	0	Δ
Aphakic	0	*	*
Pseudophakic1,2,3	0	0	*

O: Measured value is displayed.

 \triangle : May not be displayed.

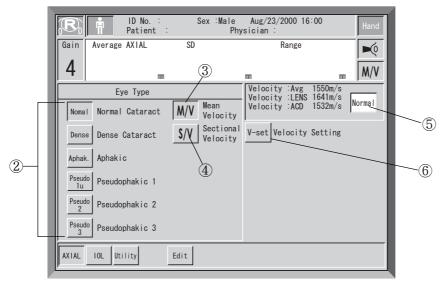
*****: Not displayed.

The axial length calculation can be chosen from the method using "average sound velocity" or "sectional sound velocity" only in case an incipient cataract is selected as the type of the eye to be measured.



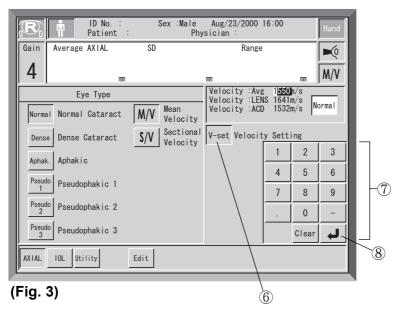
(Fig. 1)

1) Press the setting key ① of the eye type to be measured, to switch to the setting screen. (Fig. 2)



(Fig. 2)

- 2) Press the setting key ② of the eye type to be measured for setting.
- 3) When selecting "Normal", choose the axial length calculation method of "Mean Velocity (M/V)" ③ or "Sectional Velocity (S/V)" ④.
- 4) When not changing the converted sound velocity, press the measuring eye type setting key ⑤ to return the screen mode to the Measurement screen (Fig. 1) to end the operation. When changing the converted sound velocity, press the Sound Velocity Setting key ⑥ to change to the Input screen (Fig. 3).



- 5) Inputting of the converted sound velocity is made with the number keys ⑦.
- 6) When setting the input information by Enter key ®, the following items are ready for measurement.

[Inputting Range]

■ Normal (Average ultrasound velocity)

Axial length average ultrasound velocity (Avg): 1500 to 1600 m/s Lens ultrasound velocity (LENS): 1540 to 1740 m/s Anterior chamber depth ultrasound velocity (ACD):1430 to 1630 m/s

■ Normal (Sectional ultrasound velocity)

Lens ultrasound velocity (LENS): 1540 to 1740 m/s
Anterior chamber depth ultrasound velocity (ACD): 1430 to 1630 m/s
Vitreous body ultrasound velocity (Vit): 800 to 2000 m/s

■ Dense Cataract

Axial length average ultrasound velocity (Avg): 1500 to 1600 m/s Lens ultrasound velocity (LENS): 1540 to 1740 m/s Anterior depth ultrasound velocity (ACD): 1430 to 1630 m/s

■ Aphakic

Axial length average ultrasound velocity (Avg): 1430 to 1630 m/s

■ Pseudophakic

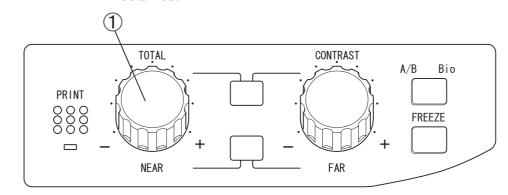
IOL ultrasound velocity (LENS): 800 to 3000 m/s
Vitreous body ultrasound velocity (Vit): 800 to 2000 m/s
Anterior chamber depth ultrasound velocity (ACD): 1430 to 1630 m/s
IOL thickness (Thickness): 0.10 to 4.00 mm

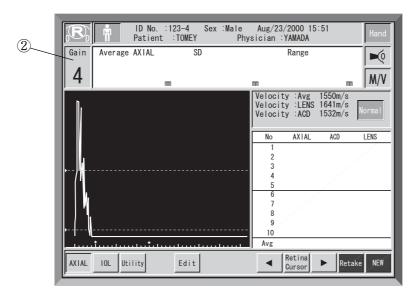
- 7) After setting he converted sound velocity, press the sound velocity setting key ⑥ to return the screen to the mode to the Eye Type Setting screen (Fig. 2).
- 8) Press the Eye Type Setting key ⑤ to return the mode to the Measurement screen (Fig. 1). Thus set eye type and sound velocity are displayed at ① and the axial length calculation method is displayed at ⑨.

c) Setting of gains

This function will be applied only on selected eye to be measured (OD or OS). The setting for both eyes cannot be changed automatically. The setting for each eye should be properly selected, according to the conditions.

The height of the waveforms is adjusted with the gains which are set in eight steps. The larger the gain is caused, the higher the waveforms are obtained.





Turn the gain adjusting volume ① to set the gain values. Set gain values are displayed in the left upper part ② of the Monitor screen.

d) ID number/patient's name/patient's gender/physician's name

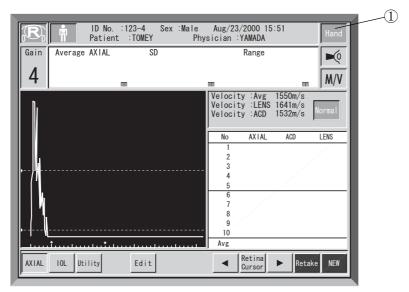
See "3.3.4 a) Entering of ID number, patient's name, patient's gender, and physician's name", or "3.3.5 ID inputting from external connection inputting devices (barcode reader, etc.)"

e) Setting of the measuring method

Note ■ This function will be applied only on selected eye to be measured (OD or OS). The setting for both eyes cannot be changed automatically. The setting for each eye should be properly selected, according to the conditions.

Select one of the three measuring method which suits the patient as well as the measuring application.

- Hand measurement (Hand probe)
 Select "Hand measurement" when taking measurement by holding the probe with hand.
- Chin measurement (Chin rest measurement)
 Select "Chin measurement" when taking measurement by using the chin rest.
- Manual measurement
 Select "Manual measurement", if measurement is difficult
 with hand or used with the Chinrest.



Set the manual measurement by pressing the measurement method setting key ①. "Hand measurement", "Chin measurement", or "Manual measurement" is alternately set by continuously pressing this key.

Selection of the contact mode/the immersion mode

See "3.11.3 1) Selection of the contact mode/immersion mode".

3.6.4 Confirmation of operation



Note Neither of measuring nor calibrating of this instrument can be given with this test piece.

The operational confirmation of this instrument is given with the test piece supplied for axial length measurement.

- 1) Set the type of the eye to be measured at "Aphakic".
- 2) Wet the surface of the test piece with water and next apply the biometry probe to the test piece at a right angle, so measurement will start.

3.6.5 Preparation for measurement

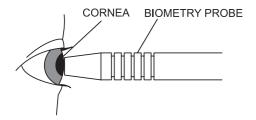


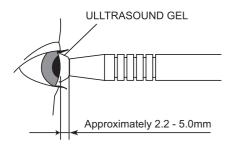
Note ■ Patient's cooperation is necessary for smooth measurement. Prior to measurement, explain the measurement method and have him sufficiently relax himself.

- 1) Confirm the measuring conditions which have been set, and check the operation as needs.
- 2) Give ophthalmic anesthesia solution to the eye to be examined. In case of the examination using the chin rest, adjust the chair, optical table, and the chin rest. In case of using the hand holding examination, have the patient be seated in the chair or have him lie on his back.
- 3) If the measurement using the chin rest requires to help guide the other eye, install the fixed lamp onto the chin rest just in front the other eye.

3.6.6 Measurement

a) How to handle the biometry probe in the contact mode and the immersion mode





<Contact mode>

Apply the eye contacting part of the biometry probe directly to the center of the cornea at a right angle.

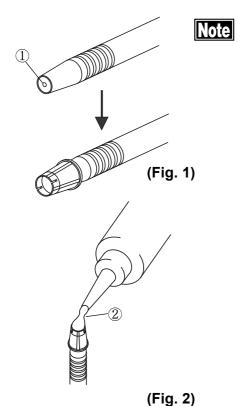
<Immersion mode>

The biometry probe can also be applied with the cornea protective media, such as water, methylcellulose gel, etc.

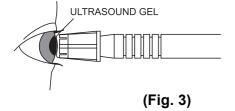
■ In case of not using the immersion attachment

Position the biometry probe at a right angle to the center of the cornea by applying the cornea protective media between the eye contacting part of the probe and the cornea so that the distance between the eye contacting part of the probe and the cornea is 2.2 to 5.0mm.

■ In case of using the immersion attachment

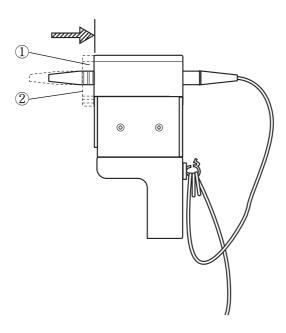


- Care must be taken not to let an air void in the cornea protective media, when using it in the end cup of the immersion attachment, which may cause measurement unable or result in incorrect measurement.
 - 1) Apply a small amount of the cornea protective media to the eye contacting part ① of the biometry probe and next attach the immersion cup onto the face of the probe. (Fig. 1)
 - 2) Put the protective media ② into the end cup of the immersion attachment in such an amount as it looks swelling. (Fig. 2)



3) Place the immersion attachment so that its head aligns to the probe axis and its optic axis and comes to the center of the cornea in such a position that the head does not touch the cornea. (Fig. 3)

b) How to use the slider when taking measurement by using the chin rest



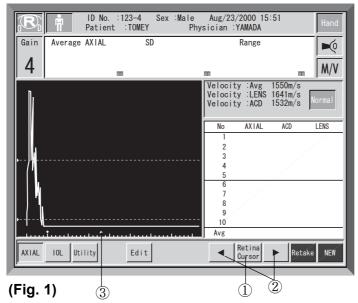
- 1) Install the biometry probe to the instrument.

 Use a sufficient length of the probe cord, or the cornea may otherwise be subjected to undue pressure by measurement. (See "3.2.3 Connecting of the Chin Rest, AL-1100.")
- 2) Press the probe against the cornea until the slider approximately aligns to the slider moving face ① and the fixed part ② while measurement, as shown in the figures. If the probe applying pressure is too weak, the axial length may be measured a little longer than its actual length due to the corneal protective media and tears. Care shall, however, be taken not to apply too excessive a pressure to the cornea with the probe.

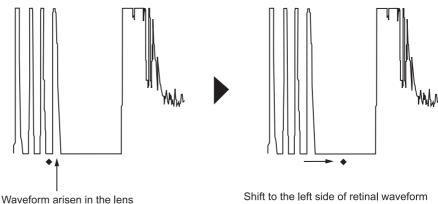
c) Selection of retinal waveform

Note ■ This function will be applied only on selected eye to be measured (OD or OS). The setting for both eyes cannot be changed automatically. The setting for each eye should be properly selected, according to the conditions.

> In case the instrument cannot recognize the ordinary waveform due to a waveform existing between the lens rear waveform and the retinal waveform, set the retinal waveform selecting cursor at the left side of the retinal waveform. The instrument thus cognizes a waveform located on the right side of the retinal waveform selecting cursor as a retinal waveform for measurement.



- In case the method using the sectional sound velocity is used for the axial length calculation method has been set, confirm that the Cursor key ① has been set at "Retina Cursor". If "Lens Cursor" has been set, press the Cursor key to change the mode for cursor.
- 2) Press the selecting cursor moving key ② to set the retinal waveform selecting cursor 3 at the left side of the retinal waveform. (Fig. 2)



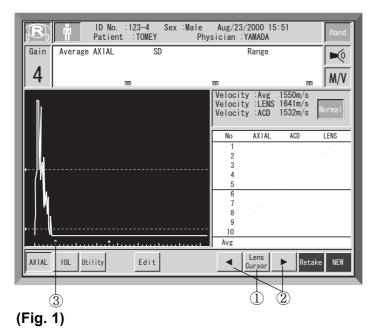
(Fig. 2)

d) Posterior Lens Spike Select

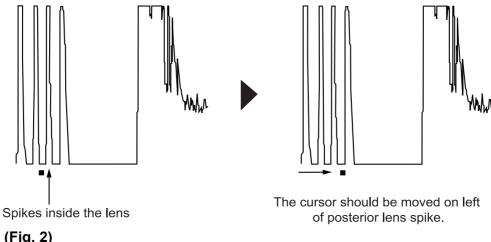
Note ■ This function will be applied only on selected eye to be measured (OD or OS). The setting for both eyes cannot be changed automatically. The setting for each eye should be properly selected, according to the conditions.

> When there are several spikes inside lens and the unit cannot pick up one as posterior lens spike, Posterior Lens Cursor should be moved on left of posterior lens spike. Then, the unit takes first spike on right of the cursor as posterior lens and shows measurement results, accordingly.

> Posterior Lens Cursor is activated only when Eye Type is selected as "Normal" and Measurement Velocity as "Sectional".

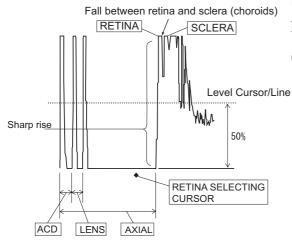


- 1) Press "Cursor" ① to change it into "Lens Cursor".
- 2) Press "Cursor Move Arrows" ② to move cursor to proper position, where it is on left of posterior lens spike.



(Fig. 2)

e) What is a good waveform



<Contact mode>

In the auto measurement, the waveforms which satisfy the following conditions ① to ③ are considered to be preferable waveforms as measurement data.

- ① The following waveforms stand high from the level cursor line position.
 - Normal
 Lens front waveform/retinal waveform
 - Dense Cataract Lens front waveform/retinal waveform
 - Aphakic Retinal waveform
 - Pseudophakic Lens front waveform/retinal waveform
- 2 The retinal waveform stands in vertical (Ultrasound wave vertically contacts with the retina.) If the wave inclines, a longer measurement tends to be resulted.
- 3 Less fluctuations with measurement data

The following items are used to check if the ultrasound waves properly catch the optical axis correctly and if the ideal waveforms are obtained.

- i) The highly rising retinal waveform indicates that related ultrasound waves have vertical contact with the retina
- ii) The highly rising lens front/rear waveforms indicate that the ultrasound waves correctly catch the optical axis.
- iii) The distinctive retinal and sclerotic waves imply that the ultrasound waves have vertical contact with the retina
 - This distinction of these two waves is not always required for the case set with high gain, since the drop (chorioid) between the two waveforms cannot be checked.
- iv) The initial waveform (corneal waveform), if having no tail behind the waves, implies that the biometry probe has direct contact with the cornea.

If tears or corneal protective media exists between the probe and the cornea, the corneal wave has a tail at the end. If this occurs, related measurement data will be unstable or resulted in longer measurement length.

Immersion echo Lens front echo Corneal echo Retinal echo Lens rear echo

<Immersion mode>

For auto measurement in the immersion mode, the following conditions are added to those for ① to ③ provided for the contact mode.

4 The corneal waveform shall be within the range of 2.2 to 5.0mm (which is shown with the broken lines in the figure).

The following items are not the conditions for taking measurement data, but used for checking if acquired waveforms are ideal or not.

Give this check together with the use of i) to iii) of the contact mode.

v) No unnecessary waveform shall be between the initial waveform and the corneal waveform.

Air void, if included in the protective media filled in the cup provided at the end of the immersion attachment or applied between the biometry probe and the cornea, causes to produce unnecessary waveforms.

3.6.7 Measurement



- Motes Make sure before taking measurement that the converted sound velocity has been set as desired, since the converted sound velocity has direct influence on measurement data.
 - Make sure also before measurement that the settings of contact mode and immersion mode have been set properly. As for the immersion mode, the protective media applied between the eye contact part of the probe and the cornea shall be in a range of approximately 2.2 to 5.0mm.
 - Care must be taken not to apply an excessive pressure to the cornea.

In case of measuring with the chin rest, care must be given not to apply an undue pressure to the cornea which exceeds the slider moving range.

Do not also apply an excessive amount of the protective media for cornea, which may otherwise affect measurement data.

- The auto measurement function is a sub-function which makes measurement easy, but is not intended for clinical evaluation for practical application.
- In case of measuring for a new patient, always press the NEW key to delete all the data for previous patient. Measurement for a new patient without deleting data taken for the previous patient, data for the new patient may be disordered with those taken for the previous patient.

a) Auto measurement (Hand/Chin)

<Hand measurement>

In the hand measurement, 15 pieces of measured data which satisfy the waveform recording conditions are taken and the data which are within the range of ± 0.2 mm to the average value are displayed in the display screen. The message of "ERROR" is displayed if measured data are largely fluctuated out of the allowable range.

The error message in this case may have been caused by improper probe application. Press the Retake key to re-take measurement. See "3.6.9 b) Deletion of measured data for single eye (Preparation for re-measurement for identical patient)".

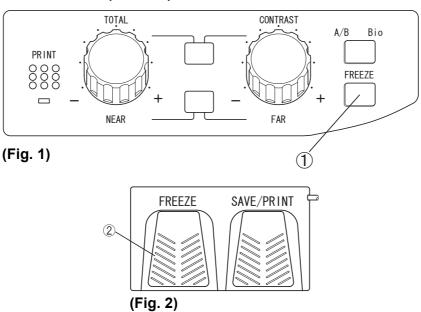
<Chin measurement>

Continue measurement until all ten pieces of measured data come within the range of ± 0.1 mm to the average. It is also noted that this measurement can be discontinued on the way of measurement.

- 1) The instrument reports it with a monitor sound of "beep" when the measuring conditions are satisfied.
- 2) The instrument automatically starts measuring data when measurement data becomes stable.
 - When the instrument completes taking data, it reports with a sound of "beep".
- 3) When 10 pieces of measured data have been taken into the instrument, it finishes measurement with a reporting sound of "beep".

The waveforms being displayed in the monitor screen are those for measured data which are closest to the average of the data.

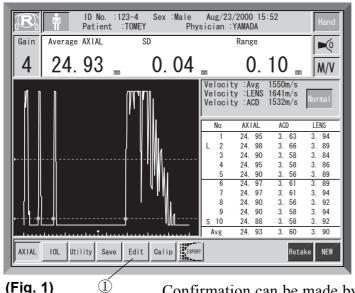
b) Manual measurement (Manual)



- 1) The instrument reports it with a monitor sound of "beep" when the measuring conditions are satisfied.
- 2) Press the FREEZE button ① or the FREEZE pedal for footswitch ② to take measured date in the instrument.
- 3) Again press the FREEZE button ① or the FREEZE pedal for footswitch ② to proceed to the next measurement.
- 4) Take measurement in a similar manner after above until 10 pieces of data are taken with a sound of "beep" for reporting the finishing of measurement.

3.6.8 Confirmation of waveforms after measurement

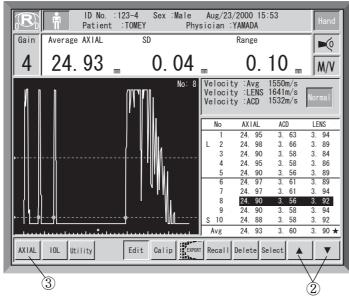
a) Display of optional waveform data



(Fig. 1)

Confirmation can be made by calling optional data from the measurement data.

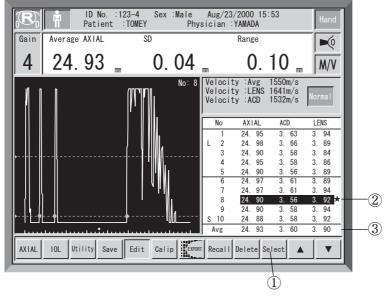
Press the Edit key ① to change the screen mode to the Measurement Data Confirmation screen (Fig. 2).



- (Fig. 2)
- Select measurement data with the Measurement Data Select key 2.
 - Selected measurement data is displayed as black/white highlighted, displaying the waveform of measured data in the waveform display part.
- 3) Press the AXIAL key ③ to return the screen mode to the Measurement screen (Fig. 1).

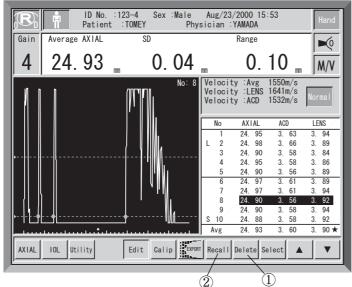
b) Selection of particular axial length data to be used for IOL power calculation

Generally, the average of measurement data saved for IOL power calculation or in the memory card is used for IOL power calculation, while optional measurement data can also be used for this purpose as well.



- 1) Optional data is displayed as black and white reversely highlighted in the Measurement Data Confirmation screen.
- 2) Press the Select key ① to select data to be used for IOL power calculation. The (★) mark ② is moved to the right side of the selected data.
- 3) In case of using the average value for IOL power calculation, move the cursor to the lowest average axial length data ③ and press the Select key ①.

c) Deletion of part of measurement data



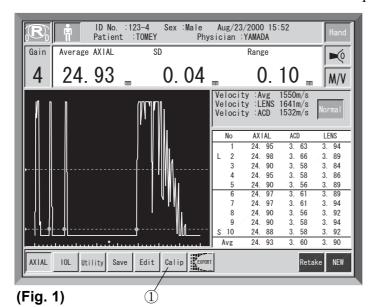
1) Optional data to be deleted is displayed as black and white reversely highlighted in the Measurement Data Confirmation screen.

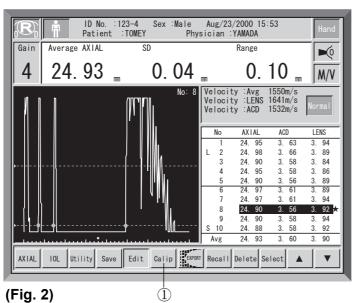
2) Press the Delete key ① for data deletion. If the Delete key is erroneously pressed, move the cursor to the number of the data pressed and next press the Recall key ② to redisplay the data. If the screen returns to the Measurement screen, the deleted data will not be redisplayed with the Recall key.

d) Caliper function

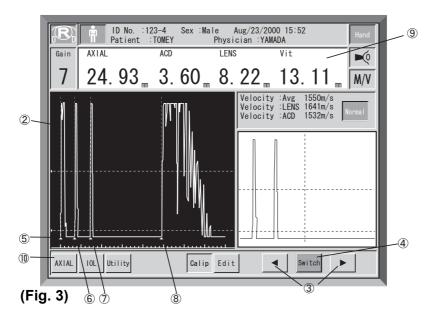
Note ■ Since the value displayed by caliper function is an approximate value, it may differ from the measured data.

The distance between two optional points can be measured. This function allows four dotted caliper lines to be displayed, to display the distance between these two optional points. The caliper lines are displayed in red for one line (as the active caliper) and in white for the other caliper lines.





1) After measurement is finished, press the Calip key ① to switch to the Caliper screen (Fig. 3), so the caliper lines ② will be displayed. A particular data can also be displayed in the Measurement Data screen (Fig. 2) for distance measurement.

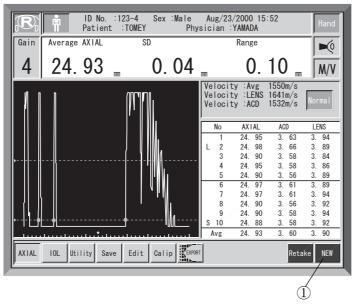


- 2) Press the Move key ③ to move the active caliper.
- 3) Each time when pressing the Switch key ④, the active caliper is changed.
- 4) The distance between No. 1 caliper line ⑤ and No. 4 caliper line ® is displayed as AXIAL ®, that between No. 1 caliper line 5 and No. 2 caliper line 6 as ACD 9, that between No. 2 line 6 and No. 3 caliper line 7 as LENS (9), and that between No. 3 caliper line (7) and No. 4 caliper line (8) as Vit (9).
- 5) Pressing of the AXIAL key ① returns the screen mode to the Measurement screen.

3.6.9 Deletion of measurement data



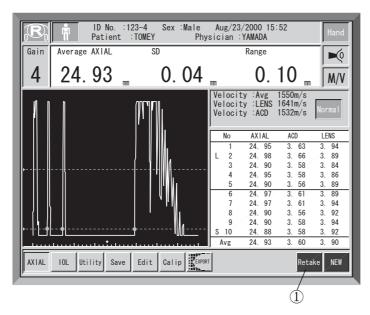
- Notes Since the data, if once deleted, will not be restored, sufficient care must be given for data deletion.
 - Be sure to press the NEW Patient key ① to delete the data for previous patients. If taking measured data for a new patient, without pressing the NEW Patient key, acquired data will not correspond to related patient information.
- a) Deletion of measurement data for both eyes (measurement preparation for a new patient)



Data deletion above is performed by pressing the NEW key ① until a sound of "beep" is made.

By this deletion, ID number, patient's name and gender are deleted as well. At the same time, K1 and K2 which are used for IOL calculation are deleted. (See "3.7 IOL power calculation".) The type of the eye to be measured is set at "Normal" and the eye to be measured is set at "R" at the same time.

b) Deletion of measurement data for single eye (re-measurement preparation for the same patient)



The measurement data for single eye only is deleted. This deletion is performed by pressing the Retake key ① for approximately one second until a sound of "beep" is made. The ID number and patient's name and gender will remain.

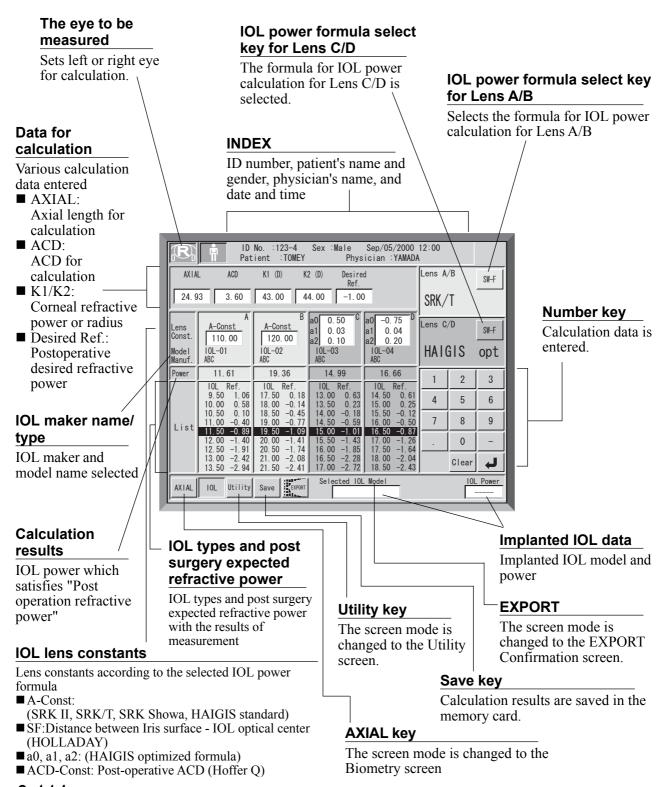
3.7 IOL power calculation



Note In case of using data measured for IOL power calculation, the physician must always examine such data.

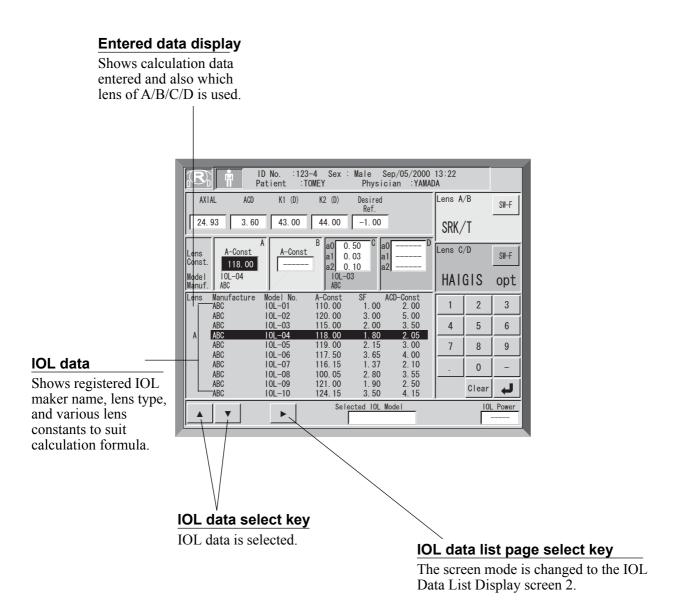
3.7.1 Screen display information

a) Entering of calculation data and display of calculation results

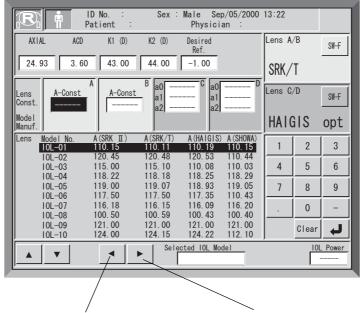


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b) IOL Data List display screen 1



c) IOL Data List Display screen 2



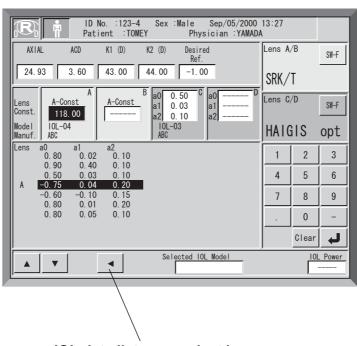
IOL data list page select key

The screen mode is changed to the IOL Data List Display screen 1.

IOL data list page select key

The screen mode is changed to the IOL Data List Display screen 3.

d) IOL Data List Display screen 3



IOL data list page select key

The screen mode is changed to the IOL Data List Display screen 2.

3.7.2 Calculation



- Notes When using the measurement results of axial length measurement for IOL power calculation, the physician shall always check the measurement results before calculation.
 - The UD-6000 may have some extent of calculation error due to the effective digits of internal calculation.
 - There may appear an imaginary number in the formula SRK/T. In this case the calculation will be done with the imaginary part as 0 and "*" will be put on the right of the calculated value.

This instrument automatically performs calculation when all necessary conditions necessary for IOL calculation, which are referred to "3.7.3 Setting of calculation formulas" and "3.7.4 Inputting of calculation data", have been inputted and calculation results will be displayed.

3.7.3 Setting of calculation conditions

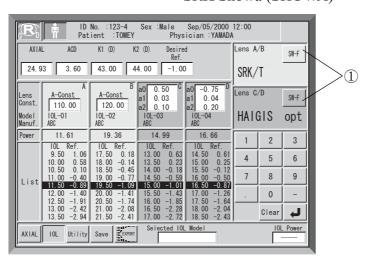
Setting of the eye type

See "3.6.3 a) Setting of the type of eye to be measured".

b) Setting of the calculation formula

Select the IOL power calculation formula from the following seven formulas.

- SRK II
- SRK/T
- HOLLADAY
- Hoffer Q
- HAIGIS optimized
- HAIGIS standard (*)
- SRK Showa (SHOWA)



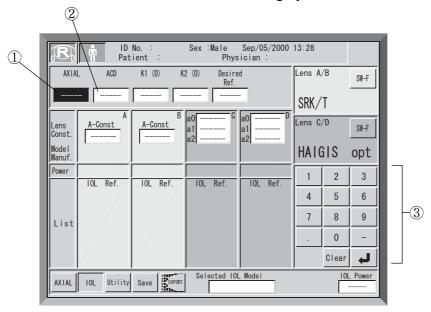
The formula setting key ① is used for setting the calculation formula. The formula is set at SRK II, SRK/T, HOLLADAY, Hoffer Q, HAIGIS optimized, or SRK SHOWA in this order every time when pressing the key.

(*) The HAIGIS standard and the SRK SHOWA formula have not been selected in the stage of shipping; therefore, select them when using the instrument, by referring to "3.11.3 f) Selection of IOL power calculation formula (IOL Formula)".

3.7.4 Inputting of calculation data

a) Inputting of axial length and anterior chamber depth (ACD)

If measurement has been finished, the AXIAL data and the ACD data have been inputted and no key input can be made. (See "3.6.8 b) Select axial length data to be used for IOL power calculation".) If these data have not been taken, input them in the following operation.



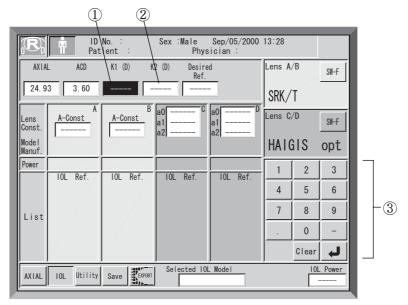
- 1) Press the AXIAL key ① or the ACD key ②, to switch to the black/white reverse-highlighted display.
- 2) Enter the date for calculation with the number key ③.

[Input range]

AXIAL: 15.00 to 40.00 mm ACD: 0.00 to 10.00 mm

3) Again press the AXIAL key ① or the ACD key ②.

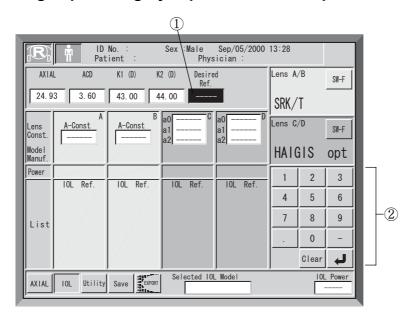
b) Inputting of corneal refractive power or corneal curvature (K1/K2)



- 1) Press the K1 ① or the K2 key ②, to change the display to the white/black reverse-highlighted mode.
- 2) Input the data for calculation with the number key ③. [Input range]

Corneal refractive power: 30.00 to 60.00 D Corneal curvature: 5.00 to 11.00 mm 3) Again press the K1 key ① or the K2 key ②.

c) Inputting of post surgery expected refractive power

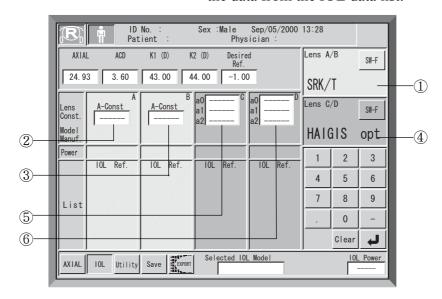


- 1) Press the Desired Ref. key ① to change the display to the black/ white reverse-highlighted mode.
- 2) Enter the data for calculation with the number key ②. [Input range]
 - 30.00 to +10.00 D
- 3) Again press the Desired Ref. key ①.

d) Inputting of the lens constant (A-Const/SF/ACD-Const/a0 · a1 · a2)

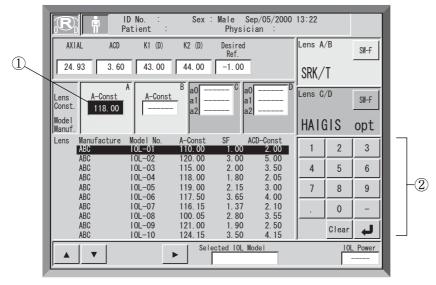
Input the IOL constants for various lenses, which shall correspond to the calculation formula used.

This instrument is capable of calculating two constants for one calculation formula. The calculation formula 1 ① is used for the lens A ② and B ③, while the formula 2 ④ is used for the lens C (5) and the D (6). The inputting procedure is performed with two ways by directly using the number key or by choosing the data from the IOL data list.



<In case of inputting with the number key>

The lens constants of a0, a1, and a2 for the HAIGIS optimized formula cannot be inputted directly with the number key. Refer to <In case of inputting from the IOL data list> mentioned below.



- 1) Press the lens constant key ① to switch the display to the white/black reverse-highlighted mode.
- 2) Input the data with the number key ②.

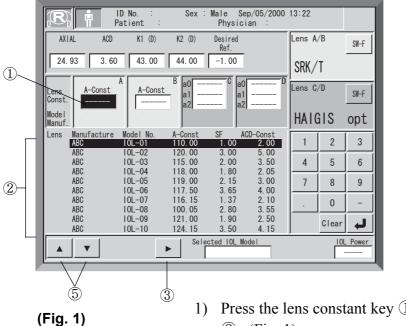
[Input range]

A-Const: 100.00 to 130.00 SF: -5.00 to +10.00

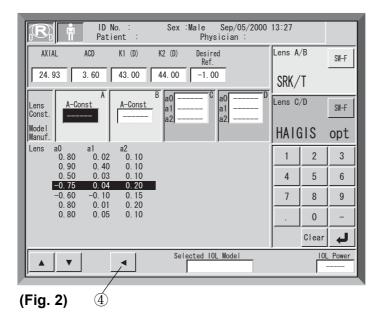
3) Again press the lens constant key ①.

<In case of imputting from the IOL data list>

In case IOL data has been registered in the "IOL Data Entry" select the data from the IOL data list.



Press the lens constant key ① to display the IOL data list ②. (Fig. 1)

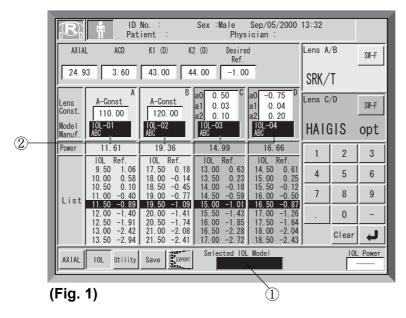


- When confirming the values of a0, a1, and a2, press the IOL data list select key ③ to display the IOL Data List Display screen 2 (Fig. 2).
- 3) Press the IOL data list page select key ①, to return the display mode to the IOL Data List Display screen 1 (Fig. 1).
- 4) Then select the data with the IOL data select key ⑤.
- 5) Press the lens constant key ①.

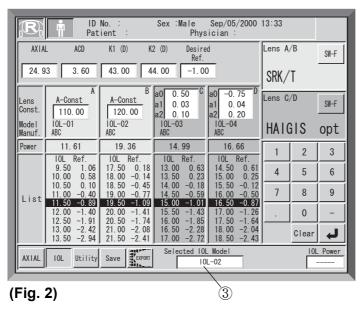
3.7.5 Saving of patient data

a) Inputting of the model name of implanted IOL (Implanted IOL Model)

The model name of an implanted IOL is saved in the memory card and used for statistical processing of patient data. Select the model name of the IOL implanted by surgery.



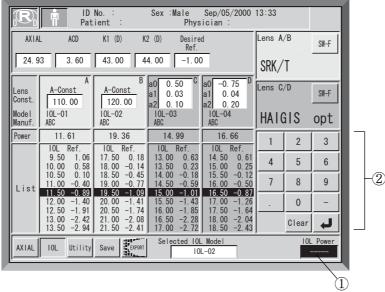
1) Press the Implanted IOL Model key ①, so the IOL model name and the maker name ② will be displayed as black/ white reverse-highlighted. (Fig. 1)



2) Next press the black/white reverse-highlighted IOL model name and maker name ②, so the IOL model name ③ will be inputted. (Fig. 2)

b) Inputting of implanted IOL power (IOL Power)

The IOL power inputted here is saved in the memory card and will be used for statistical processing of patient data. Input the implanted IOL power used for surgery.



- 1) Press the IOL Power key ①.
- 2) Use the number key ②.

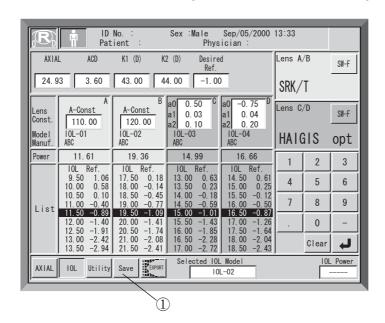
[Input range]

- -10.00 to 80.00 D
- 3) Again press the IOL Power key ①.

c) Saving of patient data

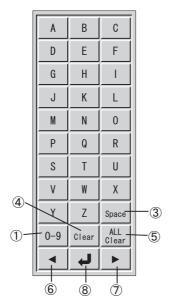


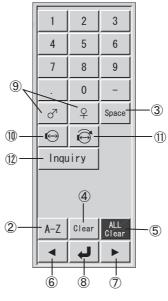
- Make sure that the memory card is inserted in the main body of the instrument.
- The saving data is controlled with the ID number. When saving measured data in the memory card, always input the ID number of the patient.



3.8 Operating of the input keys

Use the following keys shown in the following figure to enter letters and numbers.







Letter Entering Key

Number Entering Key

Ten key

① 0-9 keys: Changes to the number enter keys② A-Z keys: Changes to the letter enter keys

③ Space key: Enters spaces.

④ Clear key: Deletes data in the white/black reverse-highlighted items.

⑤ ALL Clear key: Used in the INDEX Input screen only. Deletes all the patient in-

formation, (ID number and patient's name and gender)

⑥ Left arrow marked key (◄): Moves the cursor left within the white/black reverse-highlighted items.

Right arrow marked key(►): Moves the cursor right within the white/black reverse-highlighted
 .

items.

display. If there are any consecutive items to follow, such items will be turned to its white/black reverse-highlighted display.

the "Male" is entered in the item of gender, while if pressing the \cite{Q}

key, the "Female" is entered.

① Probe mark ON/OFF key: Used only for the index enter display of the B-scan diagnosis func-

tion and the sub-function of biometry. Every time when pressing this key, the probe-mark of display/no display is alternately changed.

① Probe mark turning key: Used only for the index enter display of the B-scan diagnosis func-

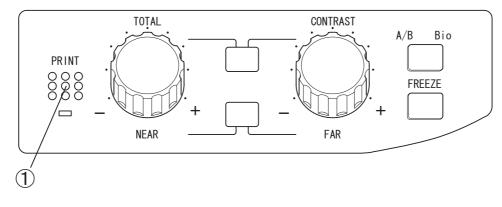
tion and the biometry sub-function. The probe mark display is

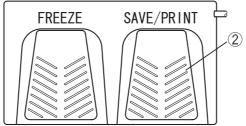
turned every time when turning the key.

② Inquiry key: Used to inquire patient information to the TOMEY Link.

3.9 Printout

3.9.1 How to print out





Printout will start when "PRINT" button is pressed or "SAVE/PRINT" pedal of the footswitch is stepped. In order to print with the footswitch, however, the footswitch should be set at "Print Only", "Store and Print", "Send and Print" or "Communication/Store/Print". See "3.8.2 h) Setting of the footswitch function".

<B-scan diagnosis function/assistant function of biometry/A-scan diagnosis function>

Displayed information in the screen is printed out as displayed by the video printer which is externally connected, but not by built-in printer.

<Biometry/IOL power calculation>

The printout of the utilities differs in its output depending on the mode to be set. (See "3.11.3 k) How to set the printout mode".)

-In case of Standard or Simple mode

The built-in printer is outputted.

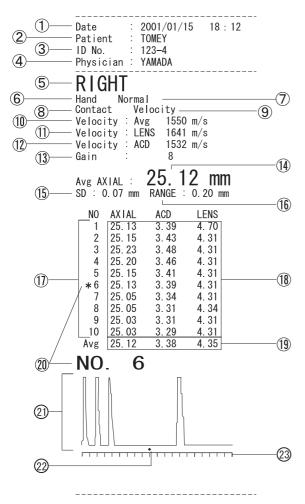
-In case of Video Printer mode

Displayed information in the screen is printed out as displayed by the video printer which is externally connected.

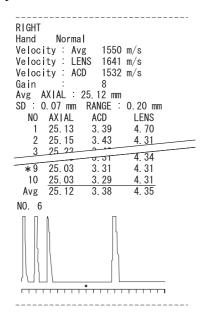
3.9.2 Contents of printout by built-in printer

a) Printout of biometry (Example of "Normal")

Standard mode



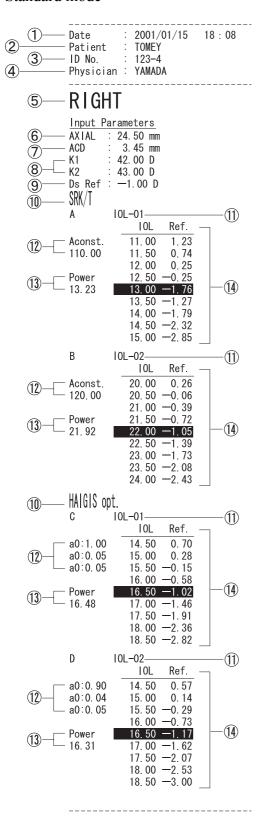
Simple mode



- ① Measuring date and time
- 2 Patient name
- ③ ID number
- 4 Physician name
- ⑤ Right/lefteye
- (6) Measurement mode
- 7 Type of eye to be measured
- 8 Contact/immersion
- Axial length calculation method
- ① Axial length average sound velocity
- ① Lens sound velocity
- ② ACD sound velocity
- Gain setting
- (4) Average axial length
- ⑤ S.D. of axial length measurements
- (6) Difference between the shortest and longest axial lengths
- Memory number
- Measurement data (axial length/ACD/lens thickness)
- Average of measurement data (Axial length/ACD/lens thickness)
- 20 Memory number of displayed waveform
- (21) Waveform
- (22) Retinal waveform select cursor
- (23) Scale (2mm per graduation)

b) Printouts of IOL power calculations (Examples of SRK/T)

Standard mode



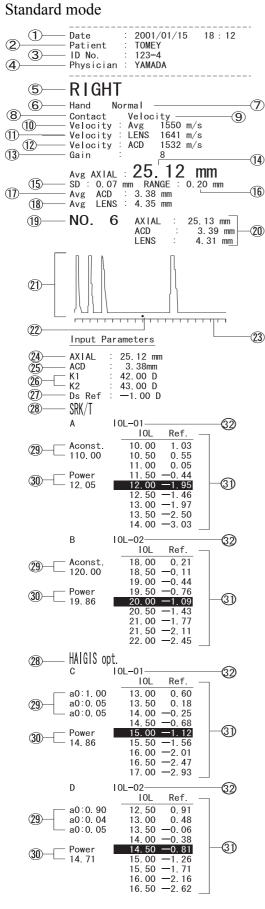
- ① Measuring date and time
- 2 Patient name
- ③ ID number
- 4 Physician name
- 5 Left/right eye for calculation
- 6 Axial length
- (7) ACD
- Corneal refractive power or corneal curvature
- ① Calculation formula name
- (1) IOL model name
- 12 Lens constants
- (13) Calculation results
- IOL standard (9 steps) and predicted postsurgery refractive power

Simple mode

RIGHT				
SRK/T				
AXIAL : ACD : K1 : Ds Ref : SRK/T	24. 50 mm 3. 45 mm 42. 00 D K2 —1. 00 D	: 43.00 D		
Α	I0L-01			
Aconst.	IOL	Ref.		
110.00	12. 50	- 0. 25		
Power	13.00	 0. 76		
13. 23	13.50	<u>-1.27</u>		
В	I0L-01			
Aconst.	I0L	Ref.		
120.00	21. 50	- 0. 72		
Power	22.00	 1. 05		
21. 92	22. 50	-1.39		
HAIGIS opt	•			
С	I0L-01			
a0:1.00	IOL	Ref.		
a1:0.05	16.00	- 0. 58		
a2:0.05	16.50	— 1. 02		
Power	17. 00	 1.46		
16. 48				
D	10L-02			
a0:0.90	10L	Ref.		
a1:0.04	16.00	 0. 73		
a2:0.05	16. 50	-1. 17		
Power	17. 00	— 1.62		
16. 31				

3.9 Printout **3-129**

Printouts for IOL power calculation after axial length measurement (Example of Normal SRK/T)



- ① Measuring date and time
- 2 Patient name
- ③ ID number
- 4 Physician name
- Right/left eye for calculation (eye for calculation)
- 6 Measuring method
- 7 Type of the eye to be measured
- 8 Contact/immersion
- 9 Axial length calculation method
- ① Axial length average sound velocity
- ① Lens sound velocity
- ② ACD sound velocity
- Gain settings
- 4 Average axial length
- ⑤ S.D. of axial length
- (6) Difference between shortest and longest axial length
- ① Average ACD
- **(8)** Average lens thickness
- Memory number of display waveform
- ② Measurement data of display waveform (Axial length/ACD/Lens thickness)
- (21) Waveform
- (22) Retinal waveform select cursor
- 23 Scale (2mm per graduation)
- (24) Axial length
- (25) ACD
- © Corneal refractive power or corneal curvature
- (27) Expected post-surgery refractive power
- (28) Calculation formula name
- (29) Lens constants
- (30) Calculation results
- (3) IOL standard (9 steps) and predicted postsurgery refractive power
- (32) IOL model name

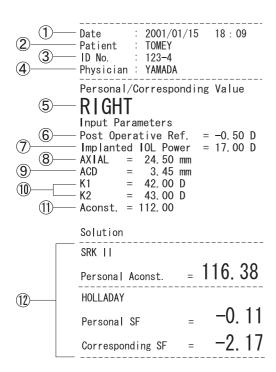
3-130 3.9 Printout

Simple mode

```
RIGHT
Hand
         Normal
Contact Velocity
Velocity: Avg 1550 m/s
Velocity: LENS 1641 m/s
Velocity :
              ACD
                      1532 m/s
Gain
Avg AXIAL: 25.12 mm
         AXIAL : 25. 13 mm
ACD : 3. 39 mm
LENS : 4. 31 mm
            25. 12 mm
3. 38 mm
AXIAL
ACD
            42.00 D K2 : 43.00 D
Ds Ref : -1.00 D
\mathsf{SRK}/\mathsf{T}
               I0L-01
Aconst.
                   I0L
                                Ref.
110.00
                 11.50
                               <del>-0.44</del>
Power
                12. 00
                                -0.95
12.05
                 12.50
                                -1.46
В
                I0L-01
                                Ref.
Aconst.
                   I OL
120.00
                 19. 50
                              <del>-0</del>.76
Power
                 20.00
                               <del>-</del>1.09
19.86
                 20.50
                              —1. 43
HAIGIS opt.
               I0L-01
a0:1.00
                  IOL
                                Ref.
a1:0.05
                 14. 50
                                -0.68
a2:0.05
                 15.00
                               -1.12_
Power
                 15.50
                               <del>-</del>1.56
16.48
D
               I0L-02
a0:0.90
                   IOL
                                Ref.
a1:0.04
                 14. 00
                                -0.38
a2:0.05
                 14. 50
                              <del>-</del>0.81
Power
                 15.00
                               -1.26
14.71
```

d) Printouts of calculation with Personal/Corresponding Value

Standard mode



- ① Measuring date and time
- 2 Patient name
- ③ ID number
- 4 Physician name
- Right/left eye to be measured (for calculation)
- ⑥ Post-surgery refractive power
- 7 Implanted IOL power
- 8 Axial length
- ① Corneal refractive power and corneal curvature
- 1 Lens constants
- (12) Calculation results

Simple mode

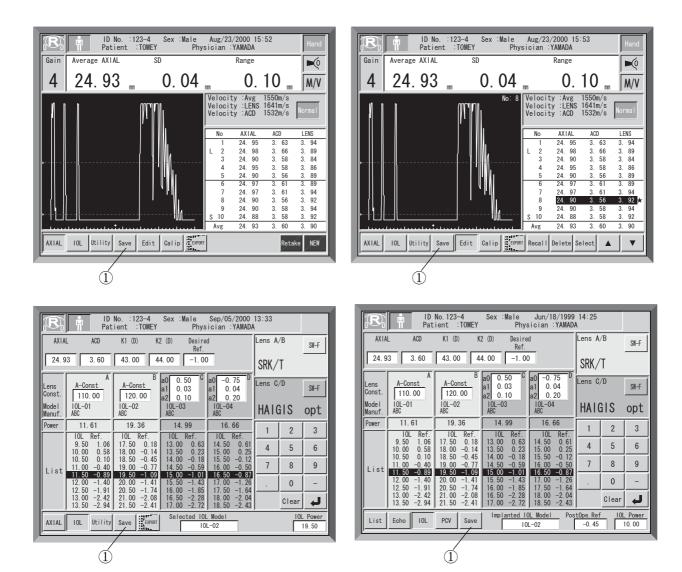
```
Personal/Corresponding Value
RIGHT
Input Parameters
Post Operative Ref. = -0.50 D
Implanted IOL Power = 17.00 D
\mathsf{AXIAL} \quad = \quad 24 \quad 50 \quad \mathsf{mm}
        = 3.45 mm
ACD
      = 42.00 D
= 43.00 D
K1
K2
Aconst. = 112.00
Solution
SRK II
Personal Aconst.
                     = 116.38
HOLLADAY
Personal SF
                           -0.11
Corresponding SF = -2.17
```

3.10 Data saving into the memory card by biometry function and IOL power calculation function

Note ■ When data is saved by this function, input the ID number for saving. The ID number is used as the file name.

3.10.1 How to save data

Press Save ① to save data into Memory Card.



3.10.2 Data to be saved in each display

Data measured for both eyes are saved in a file.

<Display after measurement>

- (1) ID number
- 2 Patient name
- 3 Physician name
- 4 Measuring date
- (5) Immersion/contact mode
- 6 Measuring method
- The type of eye to be measured
- Axial length calculation method (only in case of "Normal")
- Average sound velocity
- ① Lens sound velocity
- ① ACD sound velocity
- ② Vitreous body sound velocity
- (13) Lens thickness
- (14) Gain
- (15) Average axial length
- Average ACD
- ① Average lens thickness
- Waveform data which is the closest to that for average axial length

Data for 4 to 8 are saved for both eyes.

<Confirmation screen of measurement data>

- ① ID number
- 2 Patient name
- 3 Physician name
- 4 Measuring date
- 5 Immersion/contact mode
- 6 Measuring method
- The type of eye to be measured
- Axial length calculation method (only in case of type of eye to be measured)
- Average sound velocity
- 10 Lens sound velocity
- ① ACD sound velocity
- ② Vitreous body sound velocity
- 3 Lens thickness
- (14) Gain
- (15) Selected axial length
- (6) Selected ACD
- (17) Selected lens thickness
- **18** Selected waveform data

Data for 4 to 8 are saved for both eyes.

<IOL power calculation screen>

- ① ID number
- 2 Patient name
- 3 Physician name
- 4 Measuring date (*1)
- (5) Immersion/contact mode (*1)
- 6 Measuring method (*1)
- \bigcirc The type of eye to be measured (*1)
- Axial length calculation method (only in case the type of) eye to be measure is for "Normal)
- Average sound velocity (*1)
- ① Lens sound velocity (*1)
- ① ACD sound velocity (*1)
- ② Vitreous body sound velocity (*1)
- ① Lens thickness (*1)
- (41) Gain (*1)
- (15) Average or selected axial length (*2)
- (6) Average or selected ACD (*2)
- ① Average or selected lens thickness (*1)
- Waveform or selected waveform closest to that for average axial length (*1)
- 19 K1, K2 values
- 20 Expected refractive power
- (21) Surgery implanted IOL power
- (22) Manufacturer of implanted IOL
- (23) IOL model of surgery implanted IOL
- (24) A-constant of implanted IOL
- (25) SF value of implanted IOL
- (26) a0 value of implanted IOL
- (27) a1 value of implanted IOL
- (28) a2 value of implanted IOL
- (*1) No saving data is made if only giving IOL power calculation without measurement.
- (*2) Only user inputted data is saved if giving IOL power calculation without measurement.

Data for 4 to 28 are saved for both eyes.

<Patient data editing screen (Patient data for utility)>

- ① K1, K2 values
- ② Expected refractive power
- ③ Implanted IOL power
- 4 Manufacturer of implanted IOL
- 5 Model of implanted IOL
- 6 A-constant of implanted IOL
- T SF value of implanted IOL
- 8 a0 value of implanted IOL
- (9) al value of implanted IOL
- ① a2 value of implanted IOL
- ① Post surgery refractive power

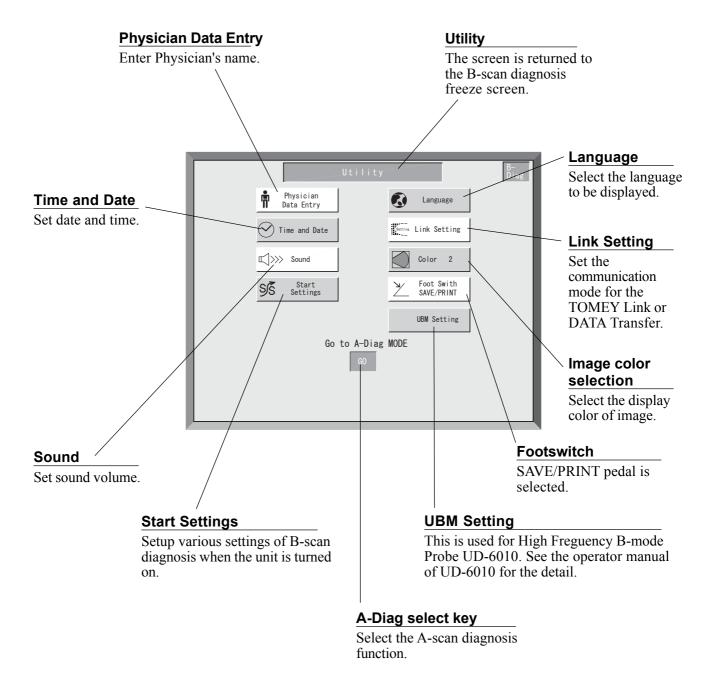
Date for ① to ① are saved for both eyes.

This screen also displays data saved in the memory card in addition to the data for ① to ①; however, data other than listed above cannot be changed and saved.

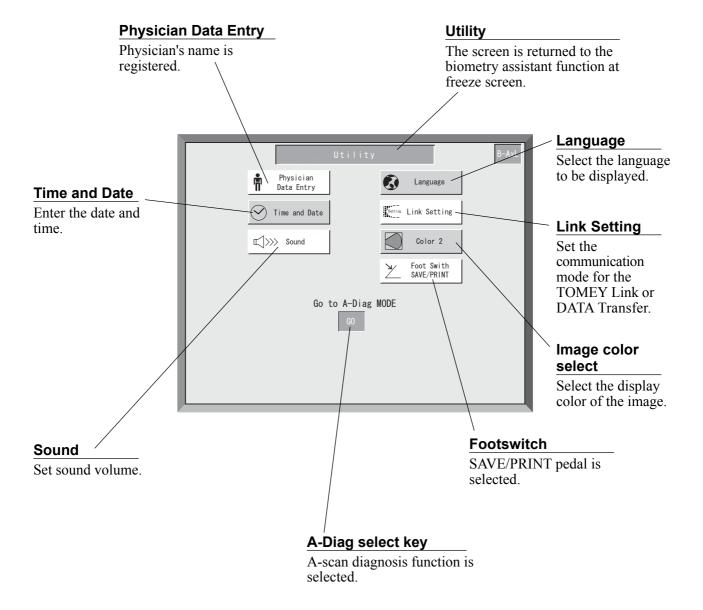
3.11 Utilities

3.11.1 Screen Information

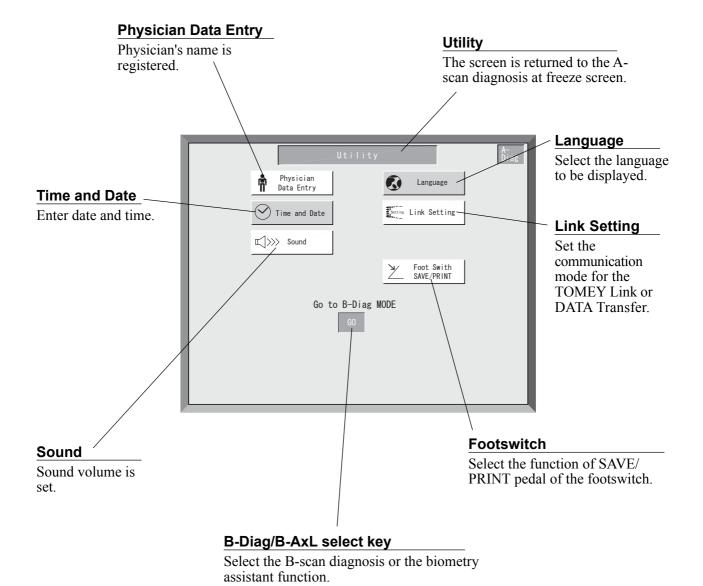
a) Utility for B-scan diagnosis



b) Utility for the assistant function of biometry

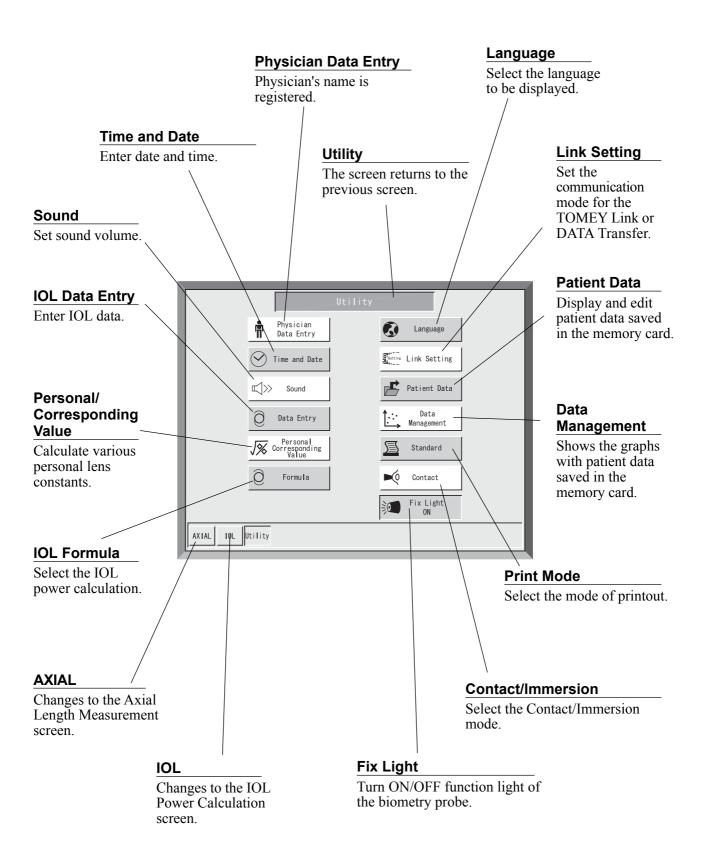


c) Utility screen for A-scan diagnosis



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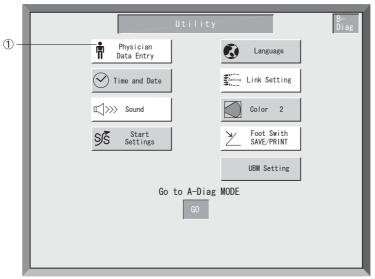
d) Utility for biometry function



3.11.2 Setting items for B-scan diagnosis assistant function/A-scan diagnosis function

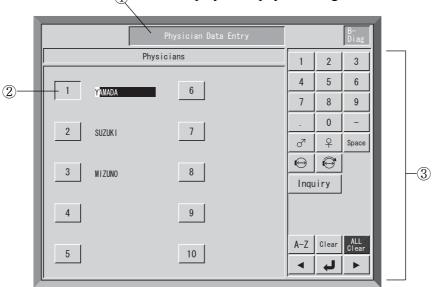
a) Registration of physician's names

If physician's names are registered in the list of physicians, the physician who performs measurement can be selected from the list of physicians by inputting the index. The name of each physician is inputted with a nmber of less than 14 letters and up to ten names at maximum can be registered.



(Fig. 1)

1) Press the Physician Data Entry key ① to change the display to the physician registration moe.

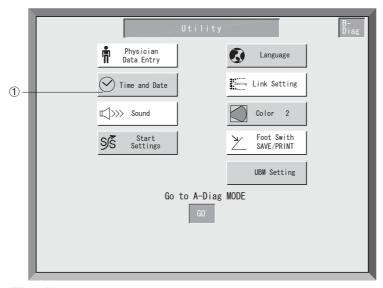


(Fig. 2)

- 2) Press the registration number in the physicians list ② to change the display tothe white/black reverse-highlighted mode.
- 3) Enter the input information with the letter keys ③ or the number keys.
- 4) Press the Physician Data Entry key ④ to return the screen to the utility mode.

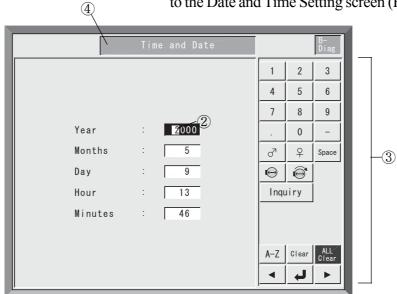
b) Time and Date

Set the date and time.



(Fig. 1)

1) Press the Time and Date key ① to change the display screen to the Date and Time Setting screen (Fig. 2).

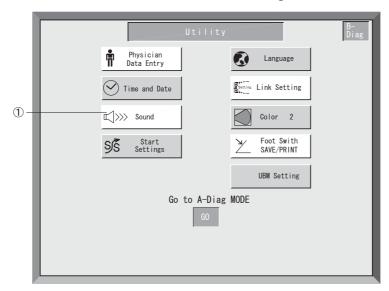


(Fig. 2)

- 2) Press the item 2 desired to change to the white/black reverse-highlighted mode.
- 3) Enter the date and time with the number key ③.
- 4) Press the Time and Date key 4 to return the screen to the Utility screen.

c) Sound volume

Set the sound volume for the input sound of the touch panel and for the warning sound.



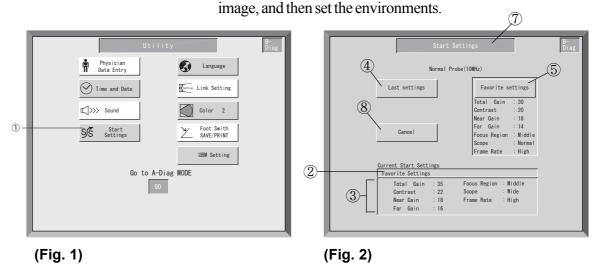
The sound volume is changed in the order of off, small, middle and large volumes, each time when pressing the Sound key ①.

d) Start settings

The setting of the initial environment when turning the power on is made by the following two ways.

- One of the two settings is given with the data set when the power was turned off the last operation (Last settings).
- The other way is to register the information as being set by which the operation is started (Favorite settings).

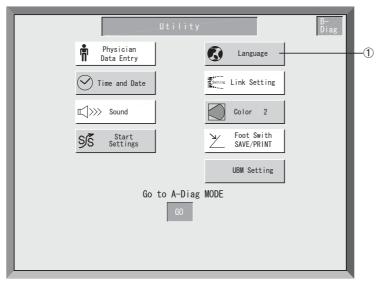
 The details are displayed below this key. In case of changing the figures, return the display to the main menu at real time, next determine each setting value by referring to the



1) Press the Start Setting key ① to change the display to the Environment Setting screen. (Fig. 2)

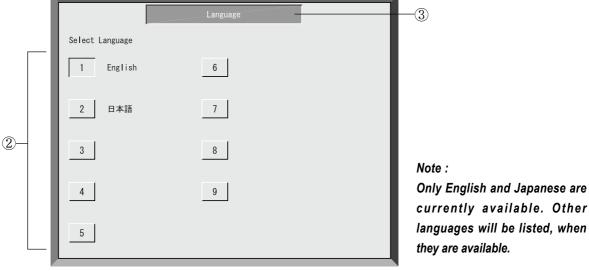
- 2) The then set information is displayed in ②. In case of the Favorite setting, the details of each set value ares displayed in ③.
- 3) Select the Last Setting key ④ or the Favorite Setting key ⑤.
- 4) Press the Cancel key 6, so the selected setting will be cancelled and the mode will be returned to the setting which has been made effective previously.
- 5) Press the Start Settings key ①, the selected input will be effective and the screen will return to the utility mode. (Fig. 1)

e) Languages



(Fig. 1)

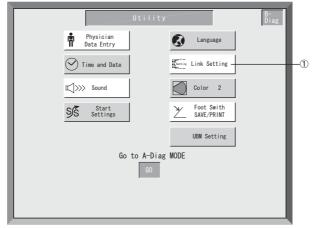
Press the Language key ① to change the display mode to the Language Setting screen (Fig. 2).



(Fig. 2)

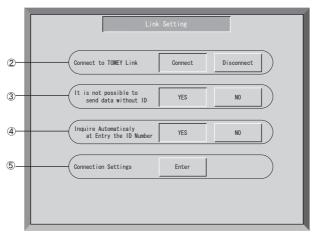
- 2) Press the number ② of language to be displayed, so the number of language selected will be as being pressed.
- 3) Press the Language key ③, the screen mode will return to the Utility screen.

f) Setting of data communications



(Fig. 1)

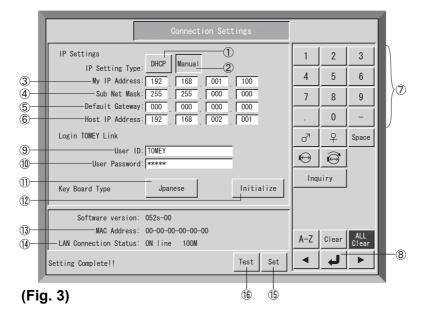
1) Press the TOMEY Link key ①.



(Fig. 2)

- 2) TOMEY Link/DATA Transfer button ② selects the connection to TOMEY Link or to DATA Transfer. Select "Connect" and these connections become available, and select "Disconnect" and these connections are cut off.
- 3) "Send only with ID" ③ selects whether the data should be sent only with the ID or not. If "Yes" is selected, the data without ID cannot be sent. If "No" is selected, the data can be sent even without ID. If "No" is selected in this item and the data without ID is sent, "NoID" will be put in the ID section of the sent data.
- 4) "Patient data is automatically inquired" ④ selects whether automatic inquiry of patient information be performed to TOMEY Link when patient ID is set. If "Yes" is selected, automatic inquiry of patient data is performed when the patient ID is set. If "No" is selected, the inquiry will be performed automatically. Patient inquiry function is available only with TOMEY Link and cannot be used with DATA Transfer. Select "No" in this item when connected to DATA Transfer.
- 5) When the button "To setting" of Communication Setting (5) is pressed for about 1 second, the screen will be changed to "Communication Setting". (Fig. 3)

<Connection Setting>



- dynamic IP) or Manual (②: stationary IP) in the IP Setting Type. If "Manual" is selected, setting can be made for own IP address ③, sub-net mask ④, default gateway ⑤, and host IP address ⑥ can be set. Touching of each input column makes it possible to input each of the above selection. This inputting is given by using the ten-key ⑦. If re-touching the input column or pressing the Enter key ⑧, the inputted contents are confirmed. If "DHCP" is selected, setting of ③ to ⑥ cannot be made. DNS is also used with DHCP. See the next item for the detail.
- 2) The Login TOMEY Link is used to set the user ID ⁽⁹⁾ and the user's password ⁽¹⁰⁾ in order to login the TOMEY Link. Inputting of these information is performed with up to 16 alpha-numeric characters. Touching of the inputting column makes it possible to input information and re-touching or pressing the Enter key ⁽⁸⁾ confirms the inputted information. This user's ID and user's password must have been registered in the TOMEY Link. As for the details, see the Operation Manual for the TOMEY Link.
- 3) Use the Key board type the type of language to be used for the external connection, ID inputting device (barcode reader, etc.). Every time when pressing the Key Board Type key ①, the of language is changed.
- 4) By pressing the Initialize key ② for approximately one second, the connection setting of the TOMEY Link is all returned to the initial condition.
- 5) Display the MAC Address ③ of this instrument.

- 6) Display the connection status (4) of LAN communications. If the LAN is in connected state, the letters of "ON Line" is displayed and the LAN speed "ON Line" at the side of it, while if in line-off state, "OFF Line" is displayed.
- 7) Press the Set key ⑤ to set the information contents as displayed. When the setting has been completed, the message of "Setting Complete" is displayed.
- 8) Press the Test key (6) to confirm the status of connection. This test is done to confirm that the physical connection has been made in normal condition. However, no confirmation can be made if the setting of IP address has been made. If physical connection is normal, the message of "Test Complete" should be displayed.

[Example]

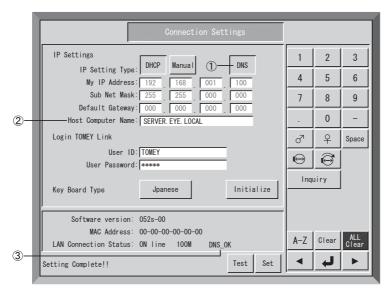
- If only this instrument and TOMEY Link server or a computer for receiving DATA Transfer, the setting can be made by following the below.
- Conformation of IP address of the computer
 Confirm and take a note of the IP address and sub net mask of
 the computer in which DATA Transfer is installed. See the operator manual of DATA Transfer for the detai.
- 2) Setting of this instrument

The table below is the example with the conditions that the computer in which DATA Transfer is installed has the IP address as [192.168.2.128] and the sub net mask as [255.255.255.0]. They are set manually.

	The computer (PC)				This instrument			
IP address	192	168	2	128	192	168	2	129
	Confirm at DATA Transfer screen				The same as the left			(*1)
Sub net mask	255	255	255	0	255	255	255	0
	Confirm at DATA Transfer screen			The same as the left				
Default gateway					0	0	0	0
					All 0			
Host IP address					192	168	2	128
					PC's IP address			

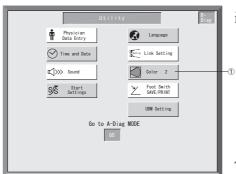
 $^{^{\}star}1$: The numbers the PC uses. (In the example arbitrary numbers between 1 and 255)

<Connection Setting : DNS>



- 1) In DHCP "DNS" key ① appears. If "DNS" key is pressed, the host IP address (Fig. 3, 6) will change to the name of the host computer ② to set the host computer with its computer name (a full name). In order to use DNS, the DNS server should be working in the LAN to be used.
- 2) After setting with DNS is completed, "DNS OK" ③ will appear. If the setting with DNS is not completed, in such a case as the name of the host computer cannot be recognized, it will not appear.

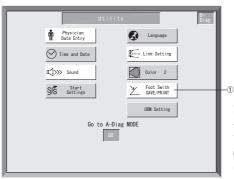
g) Selection of image colors



This instrument provides four gradation sequences for the B-scan image display.

The gradation sequences are changed each time when pressing the Image Color Select key ①.

h) Setting of the footswitch function



Set up the function of the function of the "SAVE/PRINT" pedal. Every time "Footswitch Function" key ① is pressed, the function changes in the order, "SAVE/PRINT" \rightarrow "SAVE" \rightarrow "PRINT" \rightarrow "SEND" \rightarrow "SEND/SAVE/PRINT" \rightarrow "SEND/SAVE/PRINT". Sending the data with the footswitch can be done just after freeze.

- "SAVE/PRINT": Saving the patient data into the card and printing are done at the same time.
- "SAVE" : Only saving the patient data into the card is done.
- "PRINT": Only printing is done.
- "SEND" : Only sending the patient data is done.
- "SEND/SAVE/PRINT": Sending the patient data, saving the patient data into the card, and printing are done at the same time.
- "SEND/PRINT": Sending and printing the patient data are done at the same time.
- "SEND/SAVE": Sending and saving the patient data are done at the same time.

i) Changing of the mode

See "3.5.1 Changing to the A-scan diagnosis function".

3.11.3 Setting items of biometry function/IOL power calculation function.

a) Registration of physician's names

See "3.11.2 a) Registration of physician's names".

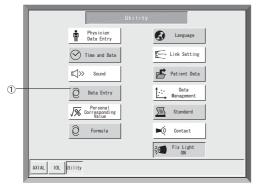
b) Setting of date and time

See "3.11.2 b) Setting of date and time".

c) Setting of sound volume

See "3.11.2 c) Setting of sound volume".

d) Registration of IOL data



(Fig. 1)

(Fig. 2)

9 C -1 0 124. 15 3. 50 4. 15 (3)

If the lens constants for various lenses re registered in the IOL data list, an appropriate lens constant can be selected for IOL power calculations, by which inputting information can be eliminated.

Up to ten items for IOL data can be registered.

Set the lens constant corresponding to each IOL power calculation formula.

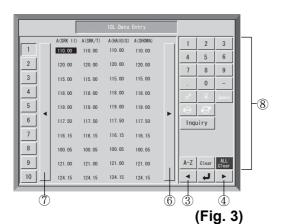
■ SRK II: A (SRK II) ■ SRK/T: A(SRK/T)

■ HOLLADAY: SF

ACD-Const ■ Hoffer Q: ■ HAIGIS optimized: a0, a1, a2 ■ HAIGIS standard: A (HAIGIS) ■ SRK SHOWA formula: A (SHOWA)

A-constant can be set for each calculation formula. If, however, not set, use A-Const (common A-constant).

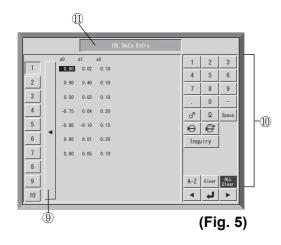
- 1) Press the IOL Data Entry key ① to change the display to the registration mode. (Fig. 2)
- 2) Press the registration key ① for desired registration number.
- 3) Change the registration item with the use of the right arrow key ③ or the left arrow key ④.



- 4) When setting the A (SRK II), A (SRK/T), A (HAIGIS), and A (SHOWA), press Page Change key ⑤ to display the Registration screen-2 (Fig. 3).
- 5) When inputting a0, a1, and a2, press the Page Change key ⑥ to display the Registration screen-3 (Fig. 4). To return to the Registration screen-1 (Fig. 2), press the Page Change key ⑦.



(Fig. 4)



- Note High optimization is required for the HAIGIS optimized formula. Special knowledge is required for determining a0, a1 and a2.
 - 6) The warnings concerning the inputting of a0, a1, and a2 (of which details are referred to the above notes) are displayed; therefore, press the OK key ® to delete the warning items.
 - 7) The screen is returned to the Registration screen-2 with the Page Change key ⑨. (Fig. 3).
 - 8) Enter the IOL data with the letter keys ①. [Types of letters and range or number of letters which can be inputted]

Manufacture: Up to 10 letters/letters and numbers
 Model: Up to 10 letters/letters and numbers
 A-Const and A-constant for each IOL power calculation formula: 100 to 130 numbers

SF: -5.00 to +10.00
ACD-Const: 0.00 to 10.00
a0: -9.99 to 9.99
a1: -0.99 to 0.99
a2: -0.99 to 0.99

a0, a1, and a2 shall satisfy the following conditions.

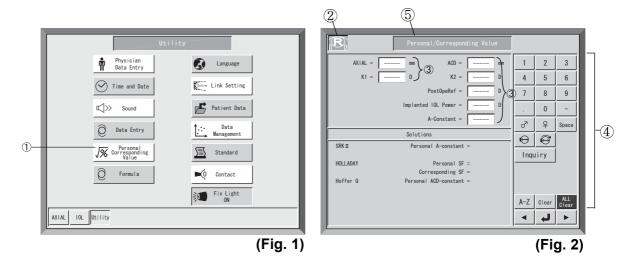
$$2 < a0 + a1 \times 3.37 + a2 \times 23.39 < 7$$

 $2 < a0 + a1 \times 2.53 + a2 \times 20.00 < 7$
 $2 < a0 + a1 \times 3.50 + a2 \times 27.00 < 7$

9) Press the IOL Data key ① to return the display to the axial length utility display mode. (Fig. 1)

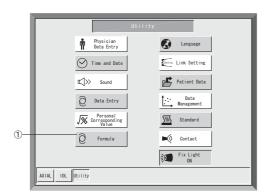
e) Calculation of personal constants

Personal A-Constant, Personal SF, Corresponding SF and Personal ACD-Const are sued for calculation.

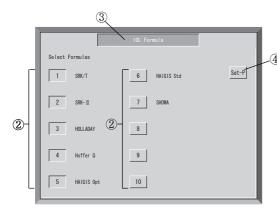


- 1) Press the Personal/Corresponding Value key ① to select the right eye or the left eye to change the screen to the Calculation screen (Fig. 2).
- 2) Press the Test Eye Select key ② to choose the right or left
- 3) Press the Item key ③ to display black/white reverse-highlighted and next enter each item with number keys 4. K1 and K2 can be entered for either of corneal refractive power or corneal curvature.
- 4) Again press the Item key ③ for confirmation.
- 5) When data necessary for calculation is inputted, the instrument automatically display calculation results.
- 6) Press the Personal/Corresponding Value key 5 to return the screen to the Axial Length Utility screen (Fig. 1).

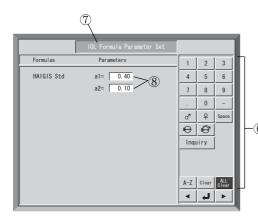
f) Selection of IOL power calculation formulas



(Fig. 1)



(Fig. 2)



(Fig. 3)

Select the calculation formulas to be used for the IOL Power Calculation screen, of which formulas can be chosen up to five formulas at the same time.

<Selection of IOL power calculation formuls>

1) Press the IOL Formula key ① to switch the display to the IOL power calcualtion formula selecting mode (Fig. 2).

At the time when the instrument is shipped, five formulas of SRK II, SRK/T, HOLLADAY, Hoffer Q, HAIGIS optimized have been set for selection.

- 2) For releasing the selection above, press the Registration Number key ②. When the selection is released, the number key is in its raised position.
- 3) Next press the IOL Formula key ③ to return the display to the mode of axial length utility (Fig. 1).

 There are the specified IOL power calculation formulas can be customized by changing the parameters for the formulas.

<Setting of the parameters for calculation formulas>

- 4) Press the Set-P key ① to switch the display to the parameter setting mode (Fig. 3).
- 5) Press the Item key ⑤ to change the display to the black/white reversed mode and next change each parameter with the number key ⑥.
- 6) Press the IOL Formula Parameter Set key 7 to return the display to the selection mode (Fig. 2) for IOL power calculation.

g) Selecting of languages

See "3.11.2 e) Selecting of languages".

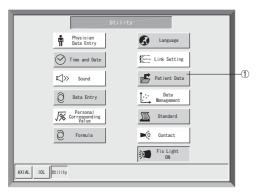
h) Setting of data communications

See "3.11.2 f) Setting of data communications.

Displaying and editing of patient data saved in the memory card

Patient data saved in the memory card is displayed and edified.

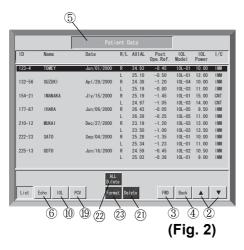
Note ■ If the List screen (Fig. 2) is being displayed, the memory card shall not be taken out the instrument. If the memory card is taken out as mentioned above, the screen will automatically be returned to the mode (Fig. 1) used before the then ongoing screen was changed.

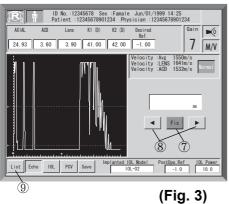


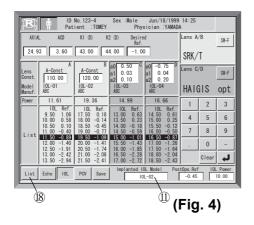
(Fig. 1)

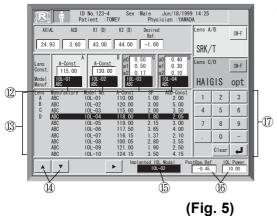
<Displaying of the patient data list>

- 1) Press the Patient Data key ① to change to the List screen (Fig. 2).
- 2) Press the Data Select key ② to display the patient data black/white reverse-highlighted. Change the pages with the FWD key ③ or the BACK key ④ as needs.
- 3) Press the Patient Data key (5) to return to the Axial Length Utility screen (Fig. 1).









<Displaying of patient data>

- 1) Press the Echo key ⑥ to display the waveform of selected patient data (Fig. 3).
- 2) The distance between the cursors is displayed with the use of the Fix key 7 and the Caliper Move key 8. (See "3.6.8 d) Caliper function".)
- 3) Press the List key ① to return the screen to the List screen (Fig. 2)".

<Edifying of patient data>

- 1) Press the IOL key ①, to display the Selected Patient Data Editing screen (Fig. 4).
- 2) When inputting the Implanted IOL Model, press the Item key ① display the part wherein the IOL model names and maker names are displayed as white/black reverse-highlighted. At the same time, the IOL data list ③ is displayed.

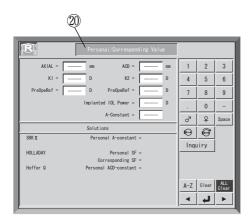
If the Item key ⑤ is again pressed after pressing the part displayed with white/black reverse-highlighted or after selecting the IOL data desired to input with the IOL Data Selecting key ⑥, selected IOL model name will be inputted.

3) When inputting the IOL Power and the Post Ope. Ref., press the Item key (6) and next change to the white/black reverse-highlighted display and enter the information with number key (7).

[Inpurt range]

IOL Power: -10.00 to 80.00 D Post Ope. Ref.: -10.00 to +10.00 D

4) Press the List key ® to return the screen display to the List screen (Fig. 2).



- <Calculation of personal lens constant>
- 1) Press the PCV key (9) to change the display to the screen for personal lens constant calculation. (Fig. 6)
- 2) If all the items are inputted, relevant calculation results will automatically be displayed.
- 3) Press the Personal/Corresponding Value key 20 to return the display to the List screen (Fig. 2).

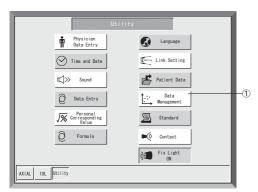
(Fig. 6)



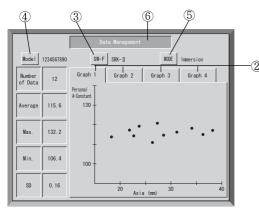
- Note No measurement data, if once deleted, can be restored. Sufficient check should be given to the data before deleting.
 - <Deleting of patient data>
 - 1) Press the Delete key (21) for approximately one second until the sound of "beep" is made, to delete patient data in the white/black-reverse highlighted display. The data thus deleted are patient data for both eyes.
 - 2) Pressing of the ALL Clear key ② for approximately one second until a sound of "beep" is made, to delete all the patient data saved in the memory card.

- Note All the data saved in the memory card is deleted when the card is formatted. The data, if once deleted by formatting, will not be restored. Sufficient check shall be given to the data saved in the memory card before formatting.
 - <Formatting of the memory card>
 - 1) If the Format key (23) is pressed for approximately one second until a sound of "beep" is made, the memory card will be formatted and the error message will disappear.

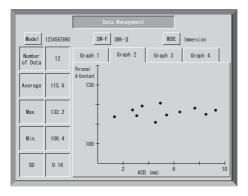
j) Statistical processing of patient data



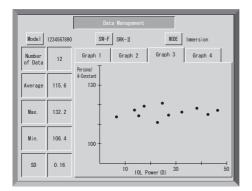
(Fig. 1)



(Fig. 2)

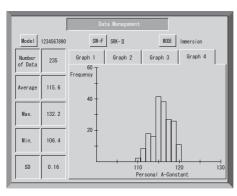


(Fig. 3)



(Fig. 4)

- This function statistically processes patient data saved in the memory card and displays them in four types of graph. The statistical processing of patient data is given by IOL Model saved in the memory card. In case different lens constants for IOLs in the model are saved in the memory card, their statistical processing is given as an identical IOL.
- 1) Press the Data Management key ① to display the graphs 1 to 4. (Fig. 2)
- 2) Press the Graph key ② to change the graphs from 1 to 4. See Table 1 for the details of the graphs. It takes a few seconds to see the first display of data.
- 3) Press the Calculation Formula Select key ③ to display the graph for its corresponding calculation formula.
- 4) Press he Model key ④ to display the graph for each model.
- 5) Press the MODE key ⑤, so Immersion, Contact, or both Immersion and Contact or Both will be selected to display the graph of the data measured by such mode.
- 6) Press the Data Management key ⑥, so the display will return to the Axial Length Utility Screen (Fig. 1).

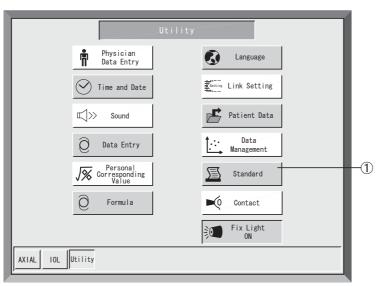


(Fig. 5)

Table 1. X-axis and Y-axis of the graph of each calculation formula

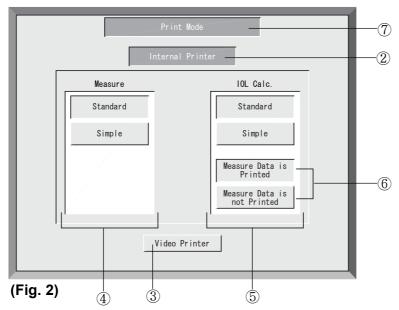
	Graph1 (Fig. 2)		Graph2 (Fig. 3)		Graph3 (Fig. 4)		Graph4 (Fig. 5)	
	x-axis	y-axis	x-axis	y-axis	x-axis	y-axis	x-axis	y-axis
SRK II	Axial length	Personal A-constant	ACD	Personal A-constant	IOL power	Personal A-constant	Personal A-constant	Frequency
HOLLADAY	Axial length	Personal SF	ACD	Personal SF	IOL power	Personal SF	Personal SF	Frequency
Hoffer Q	Axial length	Personal ACD-constant	ACD	Personal ACD-constant	IOL power	Personal ACD-constant	Personal ACD-constant	Frequency
HAIGIS std	Axial length	Personal A-constant	ACD	Personal A-constant	IOL power	Personal A-constant	Personal A-constant	Frequency
SRK (SHOWA)	Axial length	Personal A-constant	ACD	Personal A-constant	IOL power	Personal A-constant	Personal A-constant	Frequency

k) Setting of printout modes



(Fig. 1)

1) Press the Print Mode key ① to change the screen display to the Print Mode Setting screen (Fig. 2).



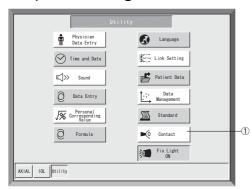
- 2) Next select the output mode whether it is from the built-in printer or the video printer. Press the Internal Printer key ② for selecting the built-in printer and press the Video Printer key ③ for the video printer.
- 3) If the built-in printer is selected, the following screen modes will furthermore be set for the Measure frame ④ and the IOL Calculation frame ⑤.

 In the Measure frame ④, the printout mode used when the PRINT key is pressed while the Axial Length Measurement Finish screen, the Edit screen, or the Patient Data Waveform Display screen is being displayed. In the IOL Calculation frame ⑤ the printout mode used when the PRINT key is pressed while the IOL Calculation Results Display screen or the Patient Data Edit screen is being displayed. The Measure data key ⑥ is used to set the axial length measurement value for the printout mode used when the IOL Power Calculation Results Display screen or the Patient Data Edit screen is being displayed and to set for "Print" or "No print" of measuring waveforms.
- 4) Select the printout mode.

■ Standard: Standard printout mode
■ Simple: Simple printout mode
(As for the details, see "3.9.2 Contents of printout".)

5) Press the Print Mode key ⑦ to return the screen display to the Utility screen (Fig. 1).

Switching of contact mode/immersion mode



The contact mode and the immersion mode are alternately changed.

1) Press the Contact/Immersion key ① in the Axial Length Utility screen (Fig. 1) to change the screen mode to the Selection Confirmation screen (Fig. 2).

(Fig. 1)

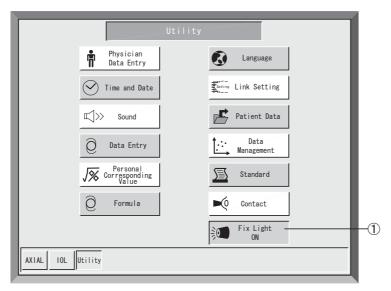


(Fig. 2)

- 2) Pressing of the OK key ② changes the mode to the Immersion mode, returning the screen to the Axial Length Utility screen (Fig. 1).
- 3) Pressing of the Cancel key ③ returns the screen to the Axial Length Utility screen (Fig. 1), without selecting the immersion mode.

Changing the immersion mode to the Contact mode is performed in a similar manner to the above.

m) Switching the A-scan probe fixation light ON/OFF



The fixation light of the axial length measuring probe is switched ON/OFF.

ON/OFF will be alternately set each time when the Fix Light key ① is pressed.

3.12 Memory card



- Use the memory card for saving the data measured by this instrument supplied. The operation of this instrument will not be guaranteed, if a memory card other than supplied with this instrument is used.
- Neither of change nor deletion of the data saved in the memory card by personal computer is allowed, since such data will not otherwise be displayed by this instrument.
- 3.12.1 How to read the information saved in the memory card by the personal computer incorporating the contents of the memory card saved in the memory card.

The data saved in the memory card of this instrument can be confirmed by the Windows personal computer providing the PC card slot.

- 1) Insert the memory card into the PC card slot of the personal computer.
 - If inserting the memory card into the personal computer for the first time, see the instruction manual for said personal computer.
- 2) Open the Explorer and make access to the removable disk where the memory card has been inserted.
- 3) The following directories are displayed by the type saved in this instrument.

Format	Directory name	File to be saved	File name	File Size (*3)
Echo (*4)	BDIAG_E	Patient data and image data of the B-scan image diagnosis function (*1)	ID number .b?? (*2)	Approx. 66K Byte
	BAXL_E	Patient data and image data of the axial length measurement sub-function (*1)	ID number .x?? (*2)	Approx. 66K Byte
	ADIAG	Patient data and waveform data of the A- scan diagnosis function (*1)	ID number .d?? (*2)	Approx. 0.8K Byte
Jpeg (*4)	BDIAG J	JPEG image file of the B-scan diagnosis function	Input file name .jpg	Approx. 35 to 70K Byte
		Text file of patient data	Input file name .txt	Approx. 0.3K Byte
	BAXL_J	JPEG image file of axial length measureing sub-function	Input file name .jpg	Approx. 35 to 70K Byte
		Text file of patient data	Input file name .txt	Approx. 0.4K Byte
Axial length (*5)	AXIALDT	Patient data and waveform data of the axial length measuring function (*1)	ID number. a ?? (*2)	Approx. 1.8K Byte

^{*1:} The data can be loaded on UD and cannot be loaded on PC. Patient data is saved as Text style, while Image and waveform as Binary

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^{*2:} Numbers are automatically typed in, on ?? part in the table

^{*3:} File Size may vary, depending on settings. Since shrinking rate changes as different image date type, above sizes are only for reference.

^{*4:} A folder as its name of Patient ID, is created under each folder for Echo and JPEG images. Each file per patient is saved under the folder. 2048 patients can be saved on each folder. 1296 data can be saved on each patient folder.

^{*5: 2048} Data can be saved on AXIALDT folder.

- 4) Files other than in the text mode can be opened by NOTEPAD (application), to confirm the details of the information contained.
- 5) JPEG image files are opened with Image Viewer software complied with JPEG.
- 6) After reading the data saved in the memory card, remove the memory card out of the personal computer. See the instruction manual for personal computer for removing of the memory card.

3.12.2 Handling of the files in the memory card

The file saved in the memory card is only intended for read. When the file is copied to the personal computer to rewrite the data, release the attribution exclusive for reading the file. Care must be taken not to release the attribution exclusive for reading the file saved in the memory card, when rewriting the data in the memory card, which may not otherwise make it impossible for the file to be displayed by this instrument.

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4. REFERENCES FOR TECHNICAL INFOR-MATION

4.1 Calculation method of axial length by biometry sub-function

Normal / Dense Cataract / Aphakic

The measured values are calculated with the average sound velocity for axial length, by using the following calculation formula.

 $L = V \cdot t/2$

L: Measured axial length

V: Sound velocity for axial length

t Time from transmitting to receiving ultrasound echo

Pseudophakic

Measured values are calculated by the following equation.

Lp = L + Th (1-1532/Vi)

Lp: Measured axial length

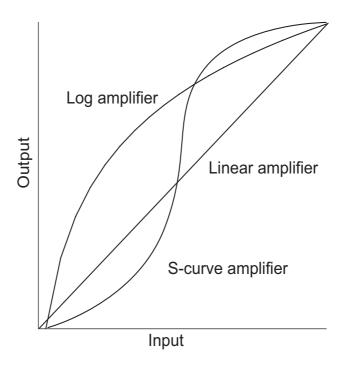
L: Axial length calculated with the biometric ultrasound velocity (axial length in an Aphakic case)

Th: Central thickness of IOL (User's input)

Vi: Sound velocity of IOL (User's input)

4.2 Amplifier characteristics of A-scan diagnosis function

The input and output characteristics of log amplifier, linear amplifier and S-curve amplifier, which are selected in A-scan diagnosis function, are as shown in the following figure.



4.3 IOL power calculation

4.3.1 SRK-IIformula

1. Implanted IOL power for Emmetropization (D)

$$P_{emme} = A1 - 0.9K - 2.5L$$

2. Implanted IOL power for Ametropization (D)

$$P_{ament} = P_{emme} - REF \cdot CR$$

3. Post surgery expected refractive power (D)

$$REF_{iol} = (P_{emme} - P) / CR$$

Where,

$$L < 20.0 \rightarrow A1 = A + 3$$

$$20.0 \le L < 21.0 \rightarrow A1 = A + 2$$

$$21.0 \le L < 22.0 \rightarrow A1 = A + 1$$

$$22.0 \leq L < 24.5 \rightarrow A1=A$$

$$24.5 \leq L \rightarrow A1=A-0.5$$

$$P_{emme} \le 14 \rightarrow CR=1.00$$

$$P_{emme} > 14 \rightarrow CR=1.25$$

A: A-constant

K: Average corneal refractive power (D) = (K1 + K2)/2

L: Axial length (mm)

P: Implanted IOL power (D)

REF: Post surgery desired refractive power

4. Personal A-Constant

$$A = P + AREF \cdot RF + 2.5L + 0.9K - COR$$
 where,

P: Implanted IOL power (D)

AREF: Power of spherical lens equal to the post surgery

refractive power (D) = S+C/2

C: Cylinder lens power (D)

S: Spherical lens power (D)

RF: Refractive factor

$$P > 16 \rightarrow RF = 1.25$$

$$P \le 16 \rightarrow RF = 1$$

L: Axial length (mm)

K: Average corneal refractive power

$$=(K1 + K2)/2$$

COR: Correction

$$L < 20 \rightarrow COR = 3$$

$$20 \leq L < 21 \rightarrow COR = 2$$

$$21 \leq L < 22 \rightarrow COR = 1$$

$$22 \leq L < 24.5 \rightarrow COR = 0$$

$$24.5 \leq L \rightarrow COR = -0.5$$

4.3.2 SRK/T

1. Implanted IOL power for emmetropization (D)

$$P_{emme} = \frac{1000 \text{na} \cdot X}{(L1 - C1)Y}$$

2. Implanted IOL power for ametropization (D)

$$P_{amet} = \frac{1000na\{X-0.001REF(V\cdot X+L1\cdot r)\}}{(L1-C1)\{Y-0.001REF(V\cdot X+C1\cdot r)\}}$$

3. Desired postoperative refraction (D)

$$REF_{iOl} = \frac{1000 \text{na} \cdot X - P \cdot Y(L1 - C1)}{\text{na}(V \cdot X + L1 \cdot r) - 0.001P(L1 - C1)(V \cdot Y + C1 \cdot r)}$$

4. Personal A-Constant

$$A = (-b + \sqrt{b^2 - 4ac})/2a$$

where,

a: $0.62467^2\alpha$

b: $0.62467 \{2\alpha (H-72.083)+\beta\}$

c: $\alpha (H-72.083)^2+\beta (H-72.083)+\gamma$

 α : P(1-nc)+0.001P·REF{V(nc-1)-r}

 $\beta \colon \ P[\text{na}\cdot \text{r} + \text{L1}(\text{nc-1}) + 0.001\text{REF}\{\text{L1}\cdot \text{r} + \text{V}\cdot \text{L1}(\text{1-nc}) - \text{na}\cdot \text{V}\cdot \text{r}\}]$

 γ : na[1000X-P·L1·r+REF{0.001P·V·L1·r-(V·X+L1·r)}]

 $X = na \cdot r - L1(nc-1)$

 $Y = na \cdot r - C1(nc-1)$

L1: Optical axial length (mm)

=L+(0.65696-0.02029L)

L: Axial length (mm)

REF: Post surgery expected refractive power (D)

r: Average corneal curvature (mm)

=337.5/K

W: Calculated corneal thickness (mm)

=-5.41+0.58412LC+0.098K

LC: Corrected axial length (mm)

 $L \le 24.2 \rightarrow LC = L$

 $L > 24.2 \rightarrow LC = -3.446 + 1.716L - 0.0237L^2$

C1: Post surgery expected ACD (mm)

=H+Ofst.

Ofst: Calculated distance between iris and optical surface of the implanted IOL (including corneal thickness)

(mm)

= ACDconst-3.336

= (0.62467A-68.747)-3.336

H: Height of the corneal dome (mm)

 $= r - \sqrt{r^2 - W^2/4}$

A: A-Constant

K: Average corneal refractive power (D)

=(K1+K2)/2

P: Implanted IOL power (D)

V: Vertex distance (mm) = 12

na: Refractive index of aqueous humor and vitreous body

= 1.336

nc: Corneal refractive index = 1.333

4.3.3 HOLLADAY

1. Implanted IOL power (D)

$$P = \frac{1000 na \{X-0.001REF(V \cdot X + L2 \cdot r)\}}{(L2-C2-SF)[Y-0.001REF\{V \cdot Y + r(C2+SF)\}]}$$

2. Post surgery expected refractive power (D)

$$P_{amme} = \frac{1000 na \cdot X \text{-P} \cdot Q \cdot Y}{na(V \cdot X + L2 \cdot r) \text{-} 0.001 P \cdot Q \{V \cdot Y + r(C2 + SF)\}}$$

Where,

 $X: na \cdot r - L2(nc-1)$

Y: $na \cdot r - (nc-1)(C2 + SF)$

O: L2-C2-SF

na: Aqueous humor and vitreous refractive index =1.336

nc: Corneal refractive index =4/3

L: Axial length (mm)

r: Average corneal curvature (mm) =337.5/K

K: Average corneal refractive power (D) =(K1+K2)/2

SF: Distance from iris to the optical center of implanted IOL (mm)

REF: Post surgery expected refractive power (D)

V: Vertex distance (mm) =12

P: Implanted IOL power (D)

L2: Corrected axial length (mm) =L+0.2

C2: Anatomical distance between ACD/corneal peak and iris (mm)

 $=0.56+Rag - \sqrt{Rag^2-AG^2/4}$

 $r < 7 \rightarrow Rag=7$

 $r \ge 7 \rightarrow Rag = r$

AG=12.5L/23.45

 $AG > 13.5 \rightarrow AG=13.5$

3. Personal SF

CQ=CQ3-CQ2

$$\begin{split} SF &= \{-BQ - \sqrt{\ BQ^2 - 4AQ \cdot CQ} \} / (2AQ) - C2 \\ Where, \\ AQ &= (nc - 1) - 0.001 AREF \{V \{nc - 1) - r\} \\ BQ &= 0.001 AREF \{L2 \cdot V \{nc - 1) - r(L2 - V \cdot na)\} \\ &- \{L2(nc - 1) + na \cdot r\} \\ CQ1 &= 0.001 AREF [V \{na \cdot r - L2(nc - 1)\} + L2 \cdot r] \\ CQ2 &= 1000 na \{na \cdot r - L2(nc - 1) - CQ1\} / P \\ CQ3 &= L2 \cdot na \cdot r - 0.001 AREF \cdot L2 \cdot V \cdot r \cdot na \end{split}$$

nc: Corneal refractive index = 4/3

na: Aqueous humor and vitreous refractive index = 1.336

r: Average corneal curvature (mm) = 337.5/K

K: Average corneal refractive power (D) = (K1+K2)/2

V: Vertex distance (mm) = 12

L: Axial length (mm)

L2: Corrected axial length = L+0.2

S: Spherical lens power (D)

C: Cylindrical lens power (D)

AREF: Power of spherical lens equal to post surgery refractive power (D) =S+C/2

P: Implanted IOL power (D)

C2: Anatomical distance between ACD/Corneal peak and iris (mm)

$$= 0.56 + \text{Rag} - \sqrt{\text{Rag}^2 - \text{AG}^2/4}$$

$$r < 7 \rightarrow Rag=7$$

$$r \ge 7 \rightarrow Rag=r$$

$$AG > 13.5 \rightarrow AG=13.5$$

4. Corresponding SF

Where,

A: A-Constant

4.3.4 Hoffer Q

1. Implanted IOL power (D)

$$P = \frac{1336}{L - C - 0.05} - \frac{1.336}{\frac{1.336}{K + R}} - \frac{C + 0.05}{1000}$$

Where,

$$R = \frac{Rx}{1-0.012Rx}$$

2. Post surgery expected refractive power with spectacles (D)

$$Rx = \frac{R}{1+0.012R}$$

Where,

$$R = \frac{1.336}{\frac{1.336}{1.000} - F} + \frac{C + 0.05}{1000} - K$$

$$C=X+Y$$

$$X=C1+0.3(L-23.5) + (\tan K)^2$$

 $Y=0.1M(23.5-L)^2tan\{0.1(G-L)^2\}-0.99166$

$$L \leq 23 \rightarrow M=+1, G=28$$

$$L > 23 \rightarrow M=-1, G=23.5$$

$$L > 31 \rightarrow L=31$$

$$L < 18.5 \rightarrow L=18.5$$

where,

P: Implanted IOL power (D)

L: Axial length (mm)

C1: Personal ACD (mm)

K: Average corneal refractive power (D)

$$=(K1+K2)/2$$

Rx: Post surgery expected refractive power with spectacles (D)

3. Personal ACD

ACD =
$$\frac{L+N-\sqrt{(L-N)^2+\frac{4\cdot1336(N-L)}{P}}}{2}-0.05$$

Where,

$$N = \frac{1336}{K + R}$$

$$R = \frac{Rx}{1-0.012ARx}$$

4. Post surgery expected ACD (ACD)

$$ACD = X+Y$$

where,

$$X=C1+0.3(L-23.5) + (\tan K)^2$$

$$Y=0.1M(23.5-L)^2tan\{0.1(G-L)^2\}-0.99166$$

$$L \leq 23 \rightarrow M=+1, G=28$$

$$L > 23 \rightarrow M=-1, G=23.5$$

$$L > 31 \rightarrow L=31$$

$$L < 18.5 \rightarrow L=18.5$$

where,

P: Implanted IOL power (D)

L: Axial length (mm)

C1: Personal ACD (mm)

K: Average corneal refractive power (D)

$$=(K1+K2)/2$$

ARx: Post surgery expected refractive power with spectacles (D)

4.3.5 HAIGIS optimized / HAIGIS Standard

1. Implanted IOL power (D)

$$P = \frac{1000na}{L - D} - \frac{na}{\frac{na}{Z} - \frac{d}{1000}}$$

$$Z = DC + \frac{REF}{1 - \frac{REF \cdot V}{1000}}$$

$$d=a0+a1 \cdot ACD+a2 \cdot L$$
 (ACD g 0)

$$d=(a0-0.241\cdot a1)+(a2+0.139\cdot a1)L$$
 (ACD = 0)

$$DC = \frac{1000(nc - 1)}{RC}$$

2. Post surgery expected refractive power (D)

$$REF_{iol} = \frac{1000(1000Y - DC \cdot X)}{V(1000Y - DC \cdot X) + 1000X}$$

Where,

$$X=d2\cdot P+1000L\cdot na-d\cdot L\cdot P$$

$$Y=na(1000\cdot na - L\cdot P+d\cdot P)$$

na: Refractive index of aqueous and vitreous body

$$=1.336$$

nc: Corneal refractive index =1.3315

A: A-Constant

RC: Average corneal curvature (mm)

$$=(K1+K2)/2$$

DC: Average corneal refractive power (D)

L: Axial length (mm)

ACD: Anterior chamber depth (mm)

REF: Post surgery expected refractive power (D)

V: Vertex distance (mm) = 12

P: Implanted IOL power (D)

a1: 0.4 -----*

a2: 0.1 ----*

* The HAIGIS optimized formula calculates with the use of registered a0, a1, and a2.

3. Personal A-Constant

$$A = \frac{d-a1 \cdot ACD - a2 \cdot L + 72.434}{0.62467} \qquad (ACD g 0)$$

$$A = \frac{d-L(a2+0.139\cdot a1)+0.241\cdot a1+72.434}{0.62467}$$
 (ACD = 0)

Where,

$$d = \frac{P(L \cdot z + 1000na) - \sqrt{P^2(L \cdot z + 1000na)^2 - 4P \cdot z(1000L \cdot na \cdot z + 1000L \cdot na \cdot P - 1000^2 \cdot na^2)}}{2P \cdot z}$$

$$Z = DC + \frac{AREF}{1 - \frac{AREF \cdot V}{1000}}$$

$$DC = \frac{1000(nc - 1)}{r}$$

a1: 0.4

a2: 0.1

RC: Average corneal curvature (mm)

ACD: Anterior chamber depth (mm)

L: Axial length (mm)

P: Implanted IOL power (D)

na: Aqueous and vitreous body refractive indexes

nc: Corneal refractive index =1.3315

DC: Average corneal refractive power (D)

AREF:Post surgery refractive power (D)

V: Vertex distance (mm) = 12

4.3.6 SRK (SHOWA)

1. Implanted IOL power (D)

$$L < 22.0$$
: P=A-2.5L-0.9K+1.4-1.45REF
 $22.0 \le L < 24.5$: P=A-2.5L-0.9K-1.67REF
 $24.5 \le L < 27.0$: P=A-2.5L-0.9K+0.71-1.25REF
 $27.0 \le L$: P=A-2.5L-0.9K-1.69REF-1.69

2. Post surgery expected refractive power (D)

$$L < 22.0 : R=(A-2.5L-0.9K+1.4-P)/1.45$$

$$22.0 \le L < 24.5 : R=(A-2.5L-0.9K-P)/1.67$$

$$24.5 \le L < 27.0 : R=(A-2.5L-0.9K+0.71-P)/1.25$$

$$27.0 \le L : R=(A-2.5L-0.9K-1.69-P)/1.69$$

3. Personal A-constant

$$L < 22.0 : A=P+2.5L+0.9K-1.4+1.45AREF$$

$$22.0 \le L < 24.5 : A=P+2.5L+0.9K+1.67AREF$$

$$24.5 \le L < 27.0 : A=P+2.5L+0.9K-0.71+1.25AREF$$

$$27.0 \le L : A=P+2.5L+0.9K+1.69AREF+1.69$$

L: Axial length (mm)

K: Average corneal refractive power (D)

REF: Post surgery expected refractive power (D)

A: A-constant

P: Implanted IOL power (D)

AREF: Post surgery refractive power (D)

4.4 Axial length calculation of Biometry

4.4.1 Normal

Axial length is calculated by the following formula. <Calculation with mean velocity>

$$L = \frac{V \cdot t}{2}$$

L: Axial length

V: Average sound velocity

t: Time

<Calculation with sectional velocity>

$$L = \frac{Vacd \cdot tacd}{2} + \frac{V lns \cdot t lns}{2} + \frac{Vvit \cdot tvit}{2}$$

L: Axial length

Vacd: ACD ultrasound velocity

Vlns: Lens ultrasound velocity

Vvit: Vitreous ultrasound velocity

tacd: ACD measurement time

tlns: Lens measurement time

tvit: Vitreous measurement time

4.4.2 Dense cataract

Measured axial length is calculated in the similar manner to that using the normal average sound velocity.

4.4.3 Aphakic

Measured axial length is calculated in the same manner to that using the normal average sound velocity.

4.4.4 Pseudophakic (1 to 3)

The factory setting of the IOL ultrasound velocity is the reference assumed from the below table. The IOL ultrasound velocity varies depending on the material, manufacturer and other conditions, such as room temperature.

	Material	IOL sound velocity (Default)
Pseudophakic1	PMMA	2718m/s
Pseudophakic2	Silicon	1049m/s
Pseudophakic3	Acryl	2200m/s

Axial length is calculated by the following formla.

$$LP = \frac{Vacd \cdot tacd}{2} + Th + \frac{Vvit \cdot tvit}{2}$$

Lp: Axial length

Th: IOL thickness in the center (Input by user)

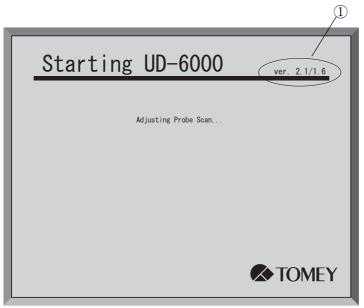
Vacd: ACD ultrasound velocity

Vvit: Vitreous ultrasound velocity

tacd: ACD measurement time

tvit: Vitreous measurement time

4.5 **Software version information**



(Fig. 1)

The Start-up screen (Fig. 1) is displayed when turning on the main switch.

Software version ① is displayed in the upper right area of the screen.

5. INSPECTION AND MAINTENANCE

5.1 Warranty

TOMEY Limited Warranty

The seller warrants this product to be free from defects in material and workmanship under the normal use of this product for one year (or the term regulated by local government) from the date of invoice, issued by the Seller to the original purchaser.

This warranty shall apply only to the original purchaser and shall NOT, in any way, be transfereable or assignable to any other party than the original purchaser.

Lamps, paper and consumable items shall not be covered by this warranty. This warranty also shall NOT apply if the product has not been installed, operated or maintained in accordance with the OPERATOR MANUAL of TOMEY CORPORATION (hereinafter called "Tomey"). Neither the Seller nor Tomey shall be liable for any damages caused by the purchaser's failure to follow instructions for proper installation, use and maintenance of the product.

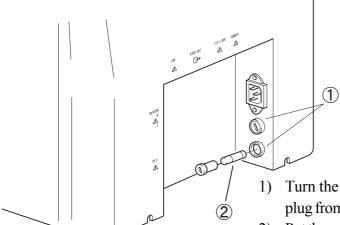
This warranty is only applicable to the new product and does NOT cover any damage resulting from or caused by accident or negligence, abuse, misuse, mishandling, improper installation, improper repair or improper modification of this product, by persons other than personnel duly authorized by Tomey, nor to a product whose serial number or batch number is removed, altered or effected.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING SPECIFICALLY, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARICULAR PURPOSE), AND ALL OTHER OBLIGATION AND LIABIITY ON THE PART OF THE SELLER AND TOMEY. NEITHER THE SELLER NOR TOMEY SHALL BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES UNDER ANY CIRCUMSCANCES OR FOR MORE THAN REPAIR, REPLACEMENT OR REFUND OF THE PURCHASE PRICE OF DEFECTIVE GOODS.

5.2 How to replace the fuse



Be sure to disconnect the power plug from the receptacle before replacing the fuse, or you may be subjected to electric shocks otherwise.



- 1) Turn the power switch off and next disconnect the power plug from the receptacle.
- 2) Put the coin in the slot provided in the fuse holder ① which is located at the rear side of the main body of the instrument. Turn the coin 90 degrees counterclockwise by lightly pushing against the fuse holder, so that the fuse holder will come out.
- 3) Hold the fuse holder with your fingers and pull it out. Remove the two fuses with the new parts.
- 4) Check to see if the fuses ② are broken, and, if broken, replace both of them with the new parts.
- 5) Load the new fuses into the fuse holder, in the reverse order of the disassembling procedure mentioned above.

5.3 Routine maintenance

5.3.1 Maintenance of the probe



- When removing the probe from the instrument, be sure to always hold the connector. Do not pull the power cord with undue force which may otherwise damage it.
- Special care shall be taken not to touch the connector, which may otherwise damage the probe.
- a) Checking of the outer appearance of the probe
 - Make sure that the eye contacting part of the probe is free of cracks, cuts, or flaws.
 - Make sure that the connector of the probe is loose and the cable is proper.

b) Cleaning

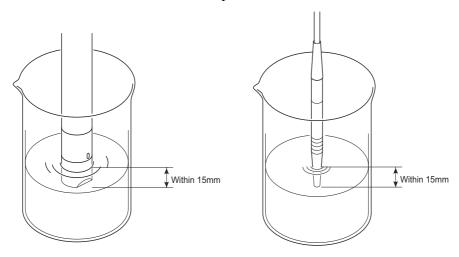


- For cleaning the eye contacting part of the probe, use absorbent cotton to avoid damaging the part.
- Do not pull the cord with an undue force, which may otherwise cause power disconnection.
- The connector jointed part shall not be wetted by cleaning.
 - For cleaning the probe, wipe the head with an absorbent cotton soaked with ethanol for disinfection and then clean the head with water.
 - Be sure to sufficiently remove water after cleaning is given.

c) Disinfection



- No sterilization by autoclave or EOG is allowed, which may otherwise greatly damage the probe.
 - Sterilization of the B-scan probe, the A-scan probe, and the Biometry probe shall be performed by first immersing the probe up to within 15mm from the eye contacting part ethanol for disinfection or sodium hypochlorite acid solvent (0.5%) for 10 to 20 minutes and then clean the probe with purified water.



5.3.2 Maintenance of the main unit



- No organic solvent, such as thinner, is allowed for cleaning the main unit of the instrument, which may otherwise harm the surface of the instrument.
- For disconnecting the card from the power source, do not pull them with undue force.
- Do not touch the connector and the connection and the connection terminals.
 - For removing the stains from the instrument body, use a piece of wet cloth after completely removing water. Wipe off the stains by lightly rubbing the surface with dry cloth. In case of hard stains, wet a piece of cloth with distilled neutral detergent and remove the solution from the cloth by tightly squeezing and next wipe the stains off by lightly rubbing the surface. Then, finalize cleaning with wet and dry cloths.

Note

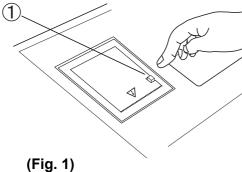
- Since the touch panel surface is not resistive to moisture, do not leave the surface with moisture or chemicals as left, which may not otherwise able to maintain the performance of the touch panel.
 - For removing stains from the monitor screen, use dry cloth. In case of hard stains, wet the cloth with a neutral detergent, next remove the water and then finish by rubbing the surface with pieces of both wet and dry cloths.
 - In case the instrument has not been used for a while, disconnect the power source plug from the receptacle and place the dust preventive cover on the instrument.

5.4 Replacing of the printer paper roll

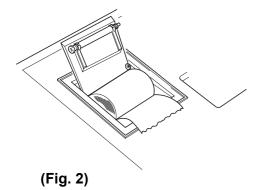
When the printer paper show the red marks on both sides, replace the paper roll in the following procedure.



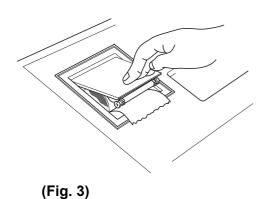
■ Pay attention not to have your hand cut, when opening or closing the printer cover.



- 1) Open the printer cover ② upward.
- 2) Remove the paper roll shaft from the printer.
- 3) Place the new paper roll into the printer with its leading end extending toward your side. (Figs. 2 and 3) Make sure that the paper face and back are turned as specified.



- 4) Securely place the printer cover securely until a sound of "click" is made.
- 5) Cut an extra part of the printer paper out.



5.5 Storing of the instrument



- Store the instrument in a place where it is not subjected to water and chemicals.
- Store the instrument in a place where it is not influenced with direct sunbeams, high temperature, high moisture, dust, salts, or sulfurcontained air.
- Care should be taken not to store the instrument in a place where it is influenced by inclination, vibration or shock.
- Do not store the instrument in a place where chemicals are stored or any gases may be generated.
 - The probe must be cleaned and dried, next placed with the cover, and then stored in the probe case.
 - When the instrument is reused a while after it is stored, make sure before using it that it operates properly.

Storing conditions

Storing room temperature: -20 to +70°C
 Relativehumidity: less than 95%

5.6 Precautions for packing materials



- The instrument shipping cardboard boxes and packing and cushion materials should be stored, since they will be necessary when the instrument is moved or transported. Do not dispose these packing and cushion materials.
- When the cardboard boxes are stored, the interior cushion materials should also be stored in the same place.
- For disposing of the packing materials, sort them by type of materials for disposal in accordance with the national and local laws and regulations.
- This instrument contains lithium battery inside. When disposing the instrument, follow the local rules and regulations.

6. TROUBLESHOOTING

Before judging that the instrument has trouble, check the following items. If it has any trouble that cannot be corrected for yourself, ask your local representative for countermeasures.



■ Do not remove the body cover from the instrument or leave it as being opened, which will otherwise cause the operator directly expose him/herself to high voltage.



- Do not give any corrective measures other than prescribed in this Manual.
- Should the trouble not be remedied by the following countermeasures, request your local distributor for inspection and repair.

<Common countermeasures>

• The power indicator does not illuminate, when turning the main switch on.

Q Cause 1 Electric power plug is not under normal condition

(Remedy Make sure if the power plug is securely connected to the power receptacle in such a manner that the plug reaches to deep inside enough.

> Make sure that the power cord is securely connected to the instrument.

> Make sure that the power cord is free of crack and flaw.

Q Cause 2 Electoric power receptacle is not normal

(Remedy Make sure that the electric power reaches to the power receptacle with proper voltage.

Q Cause 3 Broken fuse

Remedy Take the fuses and holder apart to check if the fuses are proper or broken. If broken, change the fuses as per "5.2 How to replace the fuses". If the replacement fuse is again broken second time, the instrument may have the possibility of functional disorder. If so, request your local representative for repair or inspection.

- Nothing appears on screen
 - **Q** Cause 1 The auto power off function (which automatically turns the screen off, if the instrument is out of operation for 15 minutes) is working.

Remedy Touch the screen.

- The entire screen is too dark to see.
 - **?** Cause 1 The brightness of the screen is low.
 - Remedy Turn the brightness control volume to adjust the brightness of the monitor screen. The volume is on right side of the monitor.
- No printout can be made with the video printer.
 - **?** Cause 1 Printer paper roll
 - Remedy Check if the printer paper still remains.

 Check if the printer paper is properly loaded, in accordance with the Operating Instructions for the Video Printer.
 - **Q** Cause 2 Video signal cable and remote cable
 - Remedy Make sure that the video signal cable and the remote cable are properly connected to the UD-6000 unit. See "3.2.2. b) Connecting of the video printer".
 - **?** Cause 3 The printout setup is wrong in the axial length measuring function.
 - Remedy Set the print mode at "Video Printer" with the utility of the axial length measuring function.

- The brightness and color tone of the printout from the video printer are noticeably different from those on screen.
 - **Q** Cause 1 Setup value of the video printer is not as prescribed.
 - Remedy Adjust the contrast, brightness and color tone, in accordance with the Operating Instructions for the Video Printer.
 - **Q Cause 2** The setting of UD-6000 Video Printer color monochrome select switch is not proper.
 - Remedy In case the monochrome video printer is connected to the instrument, turn the video printer color/monochrome select switch to the side of "M", while in case the color video printer is connected to the instrument, turn the select switch to the side of "C".
- Screen differs from the printout from the Video Printer.
 - **Q** Cause 1 The setting of the Printer is not correct.
 - Remedy In case of using the Video Printer having the memory function, previously stored data other than the image being displayed may be printed out•Aif only by pressing the Print button of this instrument. Set the printing mode in such a manner that data being displayed is printed only by the remote operation, in accordance with the Operating Manual of the Video Printer.
- No printout can be made by built-in Printer.
 - **?** Cause 1 Printer paper
 - Remedy Check if the printer paper is left for printing and if it is loaded properly, in accordance with the procedures prescribed in "5.4 Replacing of the built-in printer paper".
 - **?** Cause 2 Printing is made by B-scan image diagnosis function/Assistant function of biometry/A-scan diagnosis function.
 - Remedy Printing from the built-in printer can only be made by axial length measuring function.

Q Cause 3 The setting of print mode in the axial length measuring function is wrong.

(Remedy Set the printing mode at "Standard" or "Simple" in the utility of the axial length measuring function.

- The following error messages were displayed.
 - "DO NOT EXIST, TP CAL DATA"
 - "INCORRECT, TP CAL DATA"
 - "WRITE ERROR,TP CAL DATA"

2 Cause 1 Nonconforming touch panel

(Remedy After the above messages are displayed for 5 seconds, the instrument changes the screen mode to the Calibration screen. Touch the center of the white "+" marking in the black screen. When touching said center, the point disappears and shows the next "+" marking. Touch the center of the marking in the same manner until the "+" marking will not be displayed. When this operation is finished, the initial screen of the B-scan image diagnosis function is displayed to make the ordinary operation possible. After the above operation is made, the instrument will continue operation without problem until the power source s turned off. If the same error messages are followed every time when turning the power on, ask your Tomey representative for inspection and repair.

• The button which is different from that pressed in the touch panel was reacted.

Q Cause 1 The calibration for touch panel was shifted.

(Remedy Turn the power source on while pressing the PRINT button and the A/B-Bio select button. If this state elapses for 5 seconds, the screen will be changed to the calibration screen for touch panel. Then give calibration as specifed.

- "BAD CONNECTION. TP" was displayed when the power is turned on.
 - **?** Cause 1 Nonconforming touch panel.
 - Remedy Turn the power source off and ask your Tomey representative for inspection and repair.
- "Freeze" cannot be released by pressing the footswitch.
 - **?** Cause 1 Footswitch connection is not correct.
 - Remedy Make sure that the footswitch is securely locked for proper connection.
- The freeze state was made without pressing the FREEZE button or the FREEZE pedal for footswitch.
 - **Q** Cause 1 The auto freeze function was actuated.
 - Remedy In case the user's input is suspended in the real time for five minutes, the operation is automatically shifted to the freeze state. To return the operation state to real time, press the FREEZE button or the footswitch to release the freeze state.
- Pressing of the SAVE/PRINT pedal for footswitch did not save data.
 - **Q** Cause 1 The connection of the footswitch is not correct.
 - Remedy Make sure that the footswitch is connected for secured lock.
 - **Q** Cause 2 The footswitch was only set at "PRINT".
 - Remedy Set the footswitch for "SAVE", "SEND/SAVE", "SAVE/PRINT" or "SEND/SAVE/PRINT" in the procedures mentioned in "3.11.2 h) Setting of footswitch".

- No printout can be made even by pressing the SAVE/PRINT pedal for footswitch.
 - **Q** Cause 1 The connection of the footswitch is not correct.
 - Remedy Make sure that the footswitch is connected for secured lock.
 - **?** Cause 2 The footswitch is set for "SAVE", "SEND" or "SEND/SAVE".
 - Remedy Set the footswitch for "PRINT", "SEND/PRINT", "SAVE/PRINT" or "SEND/SAVE/PRINT" in the procedures prescribed in "3.11.2 h) Setting of the footswtich".
- No sending data can be made even by pressing the SAVE/PRINT pedal. for footswitch.
 - **Q** Cause 1 The connection of the footswitch is not correct.
 - Remedy Make sure that the footswitch is connected for secured lock.
 - **?** Cause 2 The footswitch is set for "SAVE", "PRINT" or "SAVE/PRINT".
 - Remedy Set the footswitch for "SEND", "SEND/SAVE", "SEND/PRINT", or "SEND/SAVE/PRINT" in the procedures prescribed in "3.8.2h) Setting of the footswitch".

<ID number input from external device>

- Even when a Patient ID is input by external device, the beep sounds without showing anything on screen.
 - **Q** Cause 1 The PS/2 port connection is not correct.
 - Remedy Correctly connect the PS/2 port of the external connection ID input device to its corresponding connector located at the rear side of the main body of the instrument.
 - **Q** Cause 2 The screen which does not make ID input is being displayed.
 - Remedy The ID inputting from the external connection ID input device can only be made when displaying the screen mentioned in "3.3.5 Inputting of the ID number from the external connection ID input device (barcode reader, etc.)". Make ID input after these screens have been displayed.
- "Illegal Code!!" appears.
 - **?** Cause 1 The letters to which the instrument do not respond were inputted from the external connection ID input device.
 - Remedy

 The letters which can be handled with this instrument are half alphameric characters (0 to9, A to Z, a to z), part of symbols (., *, /, +, -, BS, ENTER) only. If any letters other than these letters, no display can be given. If any letters other than these letters are mixed on the way of letter strings, only the letters that can be displayed will be displayd.

<Patient data inquiry to the TOMEY Link>

- "Comm. Busy!! Retry!!" is displayed.
 - **Q** Cause 1 Because of the internal communications, communications are not received temporarily.
 - Remedy Give operation again after a short time of elapse.
- "NO ID!!" is displayed.
 - **Q** Cause 1 Patient ID number has not been inputted.
 - Remedy Give communication operation after inputting the patient ID number.
- "LAN Connection ERROR!!" is displayed.
 - **Q** Cause 1 The connection of the LAN cable is not correct.
 - Remedy Check to see if the connection of the LAN cable to the connector provided at the rear side of the instrument unit and to the network side (the switching hub) is proper. Especially as for the connection of the LAN cable to the network side, ask your system administrator for correct connection.
 - **Q** Cause 2 The power of the hub is not on.
 - Remedy Check if the power of the hub wher LAN cable is connected is on.
- "Server Timeout!!" is displayed.
 - **Q Cause 1** No server's response is caused by busy condition of the TOMEY Link server.
 - Remedy Give operation again after a short time of elapse.

Q Cause 2 The connection setup of the instrument is not correct.

Remedy Give correct connection setup in the setup procedures mentioned in "3.11.2 Setting items for B-scan diagnosis asistant function/ A-scan diagnosis function f) Setting of communication". As for confirming on the details of this setting, see the Operation Manual for TOMEY Link and also ask for your System Administrator.

- "Invalid Patient ID!! (044)" is displayed.
 - **Q** Cause 1 Patient information corresponding to inputted ID number is not registered to the TOMEY Link.
 - Remedy Appropriate countermeasures shall be taken by referring to the Operation Manual for TOMEY Link, including registering of patient information.
- "Server Connection ERROR!! (042)" is displayed.
 - **?** Cause 1 The setup of the instrument is not correct.
 - Remedy Give correct connection setup in the setup procedures mentioned in "3.11.2 Setting items for B-scan diagnosis asistant function/ A-scan diagnosis function f) Setting of communication". As for confirming on the details of this setting, see the Operation Manual of TOMEYLink and also consult your System Administrator.
- "Database ERROR!! (045)" is displayed.
 - **QCause 1** ODBC setting on TOMEYLink is not correct.
 - Remedy Setup the ODBC of TOMEYLink correctly. Check the Operation Manual of TOMEYLink and consult your System Administrator.

- The following error messages are displayed.
 - "Comm. ERROR!!"
 - "Illegal Format!!"
 - "System ERROR!! (***)"
 - "Server Comm. ERROR!! (041)"
 - "Server Comm. ERROR!! (043)"
 - **?** Cause 1 These errors are caused by internal nonconformities.
 - Remedy Try again minutes later. If the same error is repeated many times, ask your representative for inspection and repair.

<Patient data transfer>

- The SEND button is not available.
 - **?** Cause 1 "CONNECT" is not selected in communication setting.
 - Remedy Make correct setting in "3.8.2 Setting items for B-scan diagnosis assistant function/A-scan diagnosis function f) Setting of data communication"
- "Comm. Busy!!" is displayed.
 - **?** Cause 1 The communication cannot be established temporarily because of internal processes.
 - Remedy Try again after a while.
- "NO ID!!" is displayed.
 - **Q** Cause 1 Patient ID number is not input.
 - Remedy Try again after inputting the patient ID number.
 - **QCause 2** Sending without ID is not set allowed.
 - Remedy Make correct setting in "3.11.2 Setting items on Utility display f) Setting of data communication".
- "OD/OS is not selected!!" is displayed.
 - **Q** Cause 1 The eye to be measured is not selected.
 - Remedy The eye to be measured is not selected.

 Choose either OD or OS for measured data in order to send it to TOMEYLink.

- "LAN Connection ERROR!!" is displayed.
 - **Q** Cause 1 LAN cable connection is not correct.
 - Remedy Make sure that the connection of the LAN cable to the connector located at the rear side of the main body and to the network side (switching hub, etc.) is proper. Especially regarding the connection to the network side, consult your system administrator for correct connection.
 - **?** Cause 2 The power of the hub is not on.
 - Remedy Check if the power of the hub where LAN cable is connected is on.
- "Server Timeout!!" is displayed.
 - **Q** Cause 1 No response from TOMEYLink server computer.
 - Remedy Make sure that the TOMEYLink server / DATA Trnsfer is running properly.
 - **Q** Cause 2 Network Setup of the instrument is not correct.
 - Remedy Give correct connection setup in the procedure mentioned in "3.11.2 Setting items of utility display f) Setting of data communication" As for confirming on the details of this setting, check the Operation Manual for TOMEYLink and also consult your System Administrator.
- "No Patient Info. on the Server!!(052)" is displayed. (Only for TOMEYLink)
 - **?** Cause 1 Requested Patient information is not registered on the TOMEYLink.
 - Remedy Appropriate countermeasures shall be taken by referring to the Operation Manual for TOMEYLink, including registration of patient information.

- "Registration Error!! (***) " appears.
 - **Q Cause 1** TOMEY Link server/ Conputer of DATA Transfer has temporary memory shortage.
 - Remedy Send it again. If this error appears often, increase RAM of the computer.
 - **Q** Cause 2 Software version is not correct.
 - Remedy Check the version of the software of the instrument, TOMEY Link/DATA Transfer and contact the place of the purchase.
 - **?** Cause 3 TOMEYLink server / DATA Transfer is not upgraded enough to respond the request.
 - Remedy TOMEYLink Server software should be upgraded into the latest version. Contact your local TOMEY Representatives.
- The following error messages come up.
 - "Data ERROR!!(***)"
 - "SYSTEM ERROR!!(***)"
 - **?** Cause 1 These error messages are caused by internal nonconformities.
 - Remedy Try again minutes later. If this error often appears, contact the place of purchase.

<Connection setting screen / connection test>

- The following error messages come up on screen.
 - "ERROR!!(***)"
 - "F-ROM ** NG!!"
 - "Illegal Format!!"
 - "SYSTEM ERROR!!(***)"
 - **Q** Cause 1 These errors are caused by wrong internal process.
 - Remedy If the same error message is repeatedly appeared, contact your representative for inspection and repair.
- "Comm. Busy!! Retry!!" shows up.
 - **Q** Cause 1 Communications are not received temporarily because of internal processes.
 - Remedy Try again after a while.
- "HTTP Error!! (003)" is displayed.
 - **@Cause 1** LAN cable connection is not correct.
 - Remedy Check if the connector in the rear side of the instrument and the connection of LAN cable to the network side (to the switching hub etc.). Especially consult your system administrator regarding the connection to the network.
 - **Q** Cause 2 The power of the hub is not on.
 - Remedy Check if the power of the hub where LAN cable is connected is on.
- "HTTP Error!! (004)" is displayed.
 - **Q** Cause 1 LAN cable connection is not correct.
 - Remedy Consult your network administrator regarding how to connect the LAN cable to the network (to the switching hub etc.) and connect it correctly.

<B-scan image diagnosis function>

- The B-scan image is not displayed.
 - **Q** Cause 1 The B-scan probe is not connected properly.
 - Remedy Make sure the probe is connected throughly deep enough to the main unit.
- The B-scan image is too dark to see.
 - **Q** Cause 1 The total gain setting is lower than it should be.
 - Remedy Turn the TOTAL volume up in order to raise the Gain.
- The ultrasound waveforms are inaccurate and unclear.
 - **Q** Cause 1 The B-scan probe connection is not correct.
 - Remedy Make sure the probe is inserted sufficiently into the main unit.
 - **?** Cause 2 The gel for ultrasound diagnosis is not used or not sufficient.
 - Remedy Apply enough amount of gel (half as big as your thumb) to the tip of the probe. If the symptom is not improved after that, try as big as your thumb or bigger.
 - **Q** Cause 3 Ambient noises
 - Remedy If there is any ambient nose sources, such as motor and laser surgery device located close to the instrument, relocate such noise generating devices sufficiently apart from the instrument.
 - **?** Cause 4 Frequent multiple echoes
 - Remedy Use sufficient amount of ultrasound gel.

• The vector-A waveform is not displayed and/or the vector-A waveform automatically disappears.

Q Cause 1 Other function, which cannot be used with the vector-A function, is working.

> The vector-A function cannot be on, while the following functions are on duty.

· Zoom function:

If the following functions are opened, the vector-A waveform will automatically be closed.

- · Ouad Windows
- · Area calculation

Remedy Close above functions, when using Vector-A waveform.

• The saved image loading function or the Quad Windows function cannot be used.

Q Cause 1 Saved data is not formatted by Echo Data, or no data is saved in the memory card.

Remedy The data, that can be displayed by this instrument, is only images saved in the memory card as Echo Data format. The data, saved as JPEG cannot be loaded on screen. When there is no data on the card, save the image as Echo data format and try again.

- Only less than 4 images can be loaded on screen with Quad Windows.
 - **Q** Cause 1 More than four images are not saved in the memory card.

Remedy Save more than four images in the memory card, if necessary.

• The motion pictures cannot track the eye, moving too fast.

Q Cause 1 Smoothing is ON.

Remedy Check if Smoothing is ON. Turn it OFF in order to get clearer images.

- TOTAL, CONTRAST volumes cannot be used.
 - **Q Cause 1** The volume controller is not switched as TOTAL/CONTRAST.
 - Remedy Press the Volume Function Select button-1 to select it to TOTAL / CONTRAST.
- NEAR / FAR volumes cannot be used.
 - **Q Cause 1** The volume controller is not swithced as NEAR / FAR.
 - Remedy Press the Volume Function select button-2 to select it to NEAR / FAR.
 - **?** Cause 2 The images are frozen.
 - Remedy NEAR / FAR Gain control works only on scanning the images. Take pictures to use NEAR / FAR Gain control. Old captured images will be lost, after starting taking pictures.
- "Probe Error!!" comes up on screen when turning the unit on or when switching to B-scan mode.
 - **?** Cause 1 The probe is not properly connected.
 - Remedy Make sure that the probe is inserted sufficiently.

<Assistant function of biometry>

- The B-scan image and the A-scan waveform are not displayed.
 - **Q** Cause 1 The connection of the B-scan probe is not correct.
 - Remedy Make sure that the B-scan probe is inserted sufficiently for secured connection.
- The B-scan images are too dark to see.
 - **Q** Cause 1 The setting value of total gain is too low.
 - Remedy Turn the TOTAL volume to raise the total gain.
- Ultrasound images are neither accurate nor clear.
 - **Q** Cause 1 The connection of the B-scan probe is not correct.
 - Remedy Make sure that the B-scan probe is inserted sufficiently for secured connection.
 - **?** Cause 2 The gel for eye protection is not used or less than necessary.
 - Remedy Apply the gel to the face of the probe. If the symptom cannot be improved, apply an additional amount of the gel.
 - **?** Cause 3 Air bubbles are included in the gel applied inside of the attachment.
 - Remedy Replace the gel in such manner that no air bubble is included in it.
 - **Q** Cause 4 Ambient noises
 - Remedy Move the instrument to a place which is away from the sources of any noises (such as from those accompanied by motor and laser surgery equipment).

- The saved image loading function cannot be used.
 - **?** Cause 1 The data was not saved in the Echo Data mode. The memory card is not saved with data.
 - Remedy The data, loaded on main unit, is only available in the memory card with the Echo Data format. The data saved by JPEG format cannot be loaded. Before using this function, please make sure that the images are stored in memory card by Echo Data format.
- TOTAL/CONTRAST volume cannot work.
 - **Q Cause 1** The volume has not selected as TOTAL/CONTRAST.
 - Remedy Press the Volume Function Select button-1 to select the function to TOTAL/CONTRAST.
- NEAR/FAR volume cannot work.
 - **?** Cause 1 The volume function has not selected as NEAR/FAR.
 - Remedy Press the Volume Function Select button-2 to select the function to NEAR/FAR.
 - **?** Cause 2 The unit is not in scanning, but in "Freeze" mode.
 - Remedy The unit should be in scanning mode in order to change NEAR/FAR setting.
- "Probe Error" comes up on screen, when switching to the assistant function of biometry.
 - **?** Cause 1 The connection of the B-scan probe was not correct
 - Remedy Make sure that the B-scan probe is inserted sufficiently.

<A-scan diagnosis function>

- A-scan waveforms will not be on screen.
 - **Q** Cause 1 The connection of the A-scan probe is not correct.
 - Remedy Check if the A-scan probe is connected properly as being locked.
 - **Q** Cause 2 The eye protective gel was not applied or less.
 - Remedy Apply an appropriate amount of corneal protective gel to the face of the A-scan probe. If the error is not improved, add the amount of the gel to apply.
- The A-scan waveform is fluctuated.
 - **@** Cause 1 Noisy condition.
 - Remedy Move away noise generating sources (such as motor, laser surgery equipment) from the instrument.
- The saved image load function cannot be used.
 - **Q** Cause 1 The data was not saved in the Echo Data mode.
 - Remedy The memory card is not saved with data. Use this function after data is saved in he memory card by image saving function.
- "Probe Error" comes up, when switching to the A-scan diagnosis function.
 - **Q** Cause 1 The A-scan probe was not connected properly.
 - Remedy Make sure the probe is inserted sufficiently.
- When changing the function mode to the A-scan diagnosis function, the message, "Please confirm that A-scan probe with blue label is connected." in the waveform window.
 - **Q** Cause 1 Correct probe (A-Scan Diagnostic) is not connected.
 - Remedy Check if the probe with blue label is properly conncected. Please note that A-scan diagnostic probe is optional probe, which does not come with main unit as standard accessory.

<Biometry function>

- Axial length measurement cannot be taken.
 - **Q** Cause 1 The biometry probe is not properly connected.
 - Remedy Connect the biometry probe until you hear click sound to be locked. See "3.2.1 b) Connecting of the biometry probe" for details.
 - **Q** Cause 2 The condition is not suitable for immersion mode.
 - Remedy The immersion mode allows taking data, when the corneal echoes are within the range of 1.8 to 3.2mm. Apply the ultrasound media(such as BSS or Ethylcellouse) to the face of the probe so that the data can be taken by immersion mode.
 - **?** Cause 3 The probe tip is directly touching cornea with the immersion mode without any ultrasound media.
 - Remedy While setting the immersion mode, use the immersion attachment or the gel for measurement in the procedures prescribed in "3.6.6 a) How to use the biometry probe in the contact or immersion mode". In case of carrying out measurement by directly touching the cornea, select it as contact mode.
- The fixation light is OFF.
 - **?** Cause 1 The fixation light is turned OFF.
 - Remedy See fixation light settings "3.11.3 m) ON/OFF switching of the fixation light for biometry probe (Fix Light)" in order to turn it ON.
- No auto measurement can be made.
 - **?** Cause 1 The measurement mode is set as "Manual".
 - Remedy Set the measurement mode as the auto measurement. "Chin" or "Hand". (See "3.6.3 e) Setting of the measuring method".

Q Cause 2 Ambient noises

Remedy If there is any noise generation source (such as motor or laser surgery equipment) located close to this instrument, move such noise source away from the instrument.

- **Q** Cause 3 The fixation light for patient is not proper.
 - Remedy Guide the patient's eye direction by using the fixation light on chin rest.
- **Q** Cause 4 The eye contacting part of the biometry probe is damaged.
 - Remedy When the probe is damaged, promptly stop using it and consult your local representative for countermeasures.
- Hand mode (the hand holding probe) cannot work well.
 - **?** Cause 1 In case of the hand holding probe, it's hard to meet all measurement conditions without any clue or experience.
 - Remedy It is not necessary to continue to take data in until automatic freeze is reached. If measurement is difficult, you can stop measurement and print or save data.
 - Remedy For stable measurement, have the patient lay himself, which helps you hold the probe stable and control the probe angle. It is also recommended to take measurement in such a manner as applying the probe weight against the probe, which does not harm the eye.
 - Remedy Lightly touch your hand holding the probe to the patient forehead or cheek to secure the position and posture of your probe holding hand.
- Manual measurement cannot work.
 - **?** Cause 1 The connection of the footswitch is not correct.
 - Remedy Connect the footswitch properly so that it is securely locked, in accordance with "3.2.1 d) Connection of the footswitch".

- **Q** Cause 2 The measurement mode is set as auto measurement "Chin" or "Hand".
 - Remedy Set the mode as "Manual". (See "3.6.3 e) Setting of the measuring method".)
- Measured data is not stable or correct, which largely differs from those measured previously.
 - **Q** Cause 1 The connection of the biometry probe is not correct.
 - Remedy Connect the biometry probe correctly. See "3.2.1 b) Connecting of the biometry probe".
 - **Q** Cause 2 The cornea is excessively compressed with the probe.
 - Remedy In case of using the chinrest, provide a sufficient length of the probe cord between the probe and the cord hook so that the cord may not be applied with undue pulling force..

 ("3.6.6. b) Handling of the slider for measurement when using the chinrest").
 - **Q** Cause 3 The position of the retinal waveform cursor is not proper.
 - Remedy Set the retinal waveform cursor on just left side at the actual retinal echo. Be careful not to contain any noise between the cursor and the retinal echo.
 - **?** Cause 4 The Biometry probe is not properly applied.
 - Remedy Place the probe vertically to the center of the cornea so that retinal echo steeply stands.
 - **?** Cause 5 The corneal protective gel is excessively applied, while setting the contact mode.
 - Remedy Excessive amount of the gel causes a gap between the probe and the cornea, resulting in longer measured data than actual values. Appropriate amount of the gel should be applied.

- **Q** Cause 6 The immersion attachment is used while the contact mode is selected. Ultrasound gel is too much.
 - Remedy Use proper amount of gel and see "3.6.6 a)" for details.
- **Q Cause 7** Biometry probe is directly attached to the cornea with Immersion mode.
 - Remedy With the immersion mode, immersion attachment must be used. See "3.6.6. a) How to handle the biometry probe in the contact/immersion modes" or by using the ultrasound gel. When measuring by directly touching the probe to the cornea, select the contact mode.
- **Q** Cause 8 The converted ultrasound velocity is way off.
 - Remedy Make sure that the velocity setting is properly selected. See ("3.6.3 b) Setting the type of the eye to be measured and converted sound velocity")
- **Q** Cause 9 The eye contacting part of the probe is damaged.
 - Remedy If such damage is found, immediately stop using the probe and contact your local representative.
- **?** Cause 10 Tear film was measured as a part of axial length due to weak pressure on probe to cornea, or the probe hits the patient eyelid to cause longer measurement result.
 - Remedy See "3.6.6. b) How to handle the slider for chinrest when using the chinrest for measurement". Push the joystick as much as the front face of moving slider and that of fixed table are aligned.
- **Q Cause 11** Patient's ocular fundus looked abnormal as staphyloma.
 - Remedy If the fundus is in a strained shape, measurement does not always correctly catch the visual axis. Measurement results vary on the probe applying manner. If such abnormality is considered, refer to "3.4 Assistant Function of Biometery" is recommended.

- Monitoring sound (beep) for axial length keeps working. Measurement is taken, even when the probe is not in use.
 - **Q** Cause 1 A drop of water or gel sticks on the probe tip.
 - Remedy Remove the water or gel from the probe by wiping it away with soft texture.
- No sound comes out from the unit.
 - **Q** Cause 1 The sound is turned OFF.
 - Remedy Turn the sound ON. See "3.11.3 c) Setting of sound volume (Sound)" for the procedure.
- There are some noises in waveform.
 - **Q** Cause 1 The probe is not properly connected.
 - Remedy Connect the biometry probe securely enough to be locked. See "3.2.1 b) Connecting of the biometry probe".
 - **?** Cause 2 The grounding of electrical power is not in use or it is not wired.
 - Remedy Check if the grounding for power plug is connected.
 - **Q** Cause 3 Ambient noises
 - Remedy When there is any noise source (such as motor and laser for surgery equipment), which is located close to the instrument, move them away from the instrument.
- "Probe Error" comes up on screen, when turning the power on or when switching the operation mode to the axial length measurement.
 - **Q** Cause 1 The probe is not properly connected.
 - Remedy Connect the probe securely enough to be locked in position. See "3.2.1 b) Connecting of the biometry probe".
- "Confirm that the biometry probe (white label) is connected." is on screen.
 - **Q** Cause 1 Correct probe is not connected.
 - Remedy Check if the right probe is connected.

<Memory card related troubles>

- Data cannot be saved in the memory card.
 - **@ Cause 1** The memory card is not properly inserted.
 - Remedy Properly insert the memory card. See "3.2.1f)
 How to insert and remove the memory card".
 - **Q** Cause 2 The ID number of the patient is not input.
 - Remedy The ID is necessary for Echo data and Biometry data savings. Type in the ID and try again.
 - **Q** Cause 3 File name is not input.
 - Remedy File name is necessary for JPEG Data storage. Type in the file name and try again.
 - **?** Cause 4 There is no enough space in the memory card. (Memory Full!! appears on screen)
 - Remedy Change the memory card with the empty card or delete unnecessary data from the card before saving new data.
- Data cannot be saved in the memory card by foot switch.
 - **Q** Cause 1 The footswitch is not properly connected.
 - Remedy Make sure that the footswitch is connected securely enough to be locked. See "3.2.1 d) Footswitch".
 - **Q** Cause 2 "SAVE" is not selected as a function of the footswitch.
 - Remedy Change the settings for the footswitch to "SAVE" or "SAVE/PRINT". See "3.11.2 h) Setting of footswitch".
- The data, saved in the memory card cannot be loaded with PC.
 - **Q** Cause 1 The memory card is not correctly inserted to PC.
 - Remedy Correctly insert the memory card into PC.
 Please refer to the operation manual of PC.

7. SPARE PARTS AND OPTION PARTS

When the following spare parts and option parts are necessary, ask your local Tomey Representatives.

7.1 Option parts

- A-scan diagnostic probe
 Please specify "A-scan disgnostic probe for UD".
- Monochrome video printer
 Contact your local dealer for the printer
- Color video printer
 Contact your local dealer for the printer
- Chin rest AL-1100
 Please specify "Chin rest AL-1100 for UD-6000".

7.2 Spare parts

Built-in printer paper
 Please specify "Built-in Printer Paper" for UD

Gel for ultrasound diagnosis
 Please specify "Gel for ultrasound diagosis".

Immersion Attachment
 Please specify "Immersion Attachment" for UD-6000.

8. SPECIFICATIONS

8.1 Specifications

- 8.1.1 B-scanDiagnosis
 - Focus
- Dynamic focus
- Frame rate

■ High: 22 frames/sec.

■ Low: 11 frames/sec.

• Maximum moving images (Assistant Function of Biometry)

■ 202 images

• Maximum waveform data taking number (A-scan diagnosis function)

■ 202 images

Image display range

■ Normal: $34.5 \text{mm} \times 46.4^{\circ}$

(Ultrasound velocity: 1,550m/s)

■ Wide: $46 \text{mm} \times 46.4^{\circ}$

(Ultrasound velocity: 1,550m/s)

Vector-A mode

■ Display step: 0.4°

Color scale

■ 240 gradation sequences

Distance measurement

<Distance accuracy between cursors>

 ± 0.5 mm

<Minimum distance unit between cursors>

Normal: 0.075 mm step (V = 1,550 m/s)

(Displayed by rounding off)

■ Wide: 0.10 mm step (V = 1,550 m/s)

Area calculation

Accuracy: $\pm \sqrt{S}$ (mm²), where S is calculated area

Image Adjustment

■ TOTAL: 1 to 60dB (Moving image display)

 ± 5 steps (at freeze)

■ CONTRAST: 1 to 60dB (Moving image display)

 ± 6 steps (at freeze)

■ NEAR: 1 to 40dB ■ FAR: 1 to 40dB

B-scan probe

Scan type: Sector scan
 Oscillator type: Annular array
 Oscillator frequency: 10MHz

■ Dimensions and weight: $25.6 \text{mm} \varnothing \times 198 \text{mm} / 400 \text{g}$

8.1.2 Assistant Function of Biometry

Converted sound velocity rates set for shipping

Normal

Axial length average ultrasound velocity: 1,550m/s

Dense

Axial length average ultrasound velocity: 1,548m/s

Aphakic

Axial length average ultrasound velocity: 1,532m/s

■ Pseudophakic

Biometric ultrasound velosity: 1,532m/s
IOL ultrasound velocity: 2,718m/s
IOL thickness: 0.8mm

Accuracy for distance between cursors

 ± 0.5 mm

• Minimum distance unit between cursors:

Normal: 0.075 mm step (V=1,550 m/s)

(Displayed by rounding off to 2nd. decimal)

■ Wide: 0.10 mm step (V=1,550 m/s)

8.1.3 A-scan Diagnosis

• A-scan diagnosite probe (Optional)

■ Type: Solid type■ Oscillator frequency: 10MHz

■ Tip diameter: $5.3 \text{mm} \emptyset \text{(flat)}$

■ Dimensions and weight: $8 \text{mm} \varnothing \times 97 \text{mm}/30 \text{g}$

8.1.4 Biometry/IOL power calculation

Measurement range

■ Axiallength: 15.00 - 40.00mm
 ■ ACD: 1.80 - 7.00mm
 ■ Lensthickness: 2.00 - 6.00mm

Accuracy of the instrument

■ Measurement accuracy: ± 0.1mm ■ Resolution: 0.01mm

Converted ultrasound velocity by factory setting

■ Axial length average ultrasound velocity

Normal: 1,550m/s
Dense Cataract: 1,548m/s
Aphakic: 1,532m/s

■ Lens ultrasound velocity

Normal: 1,641m/s Dense Cataract: 1,629m/s

■ ACD ultrasound velocity

Normal: 1,532m/s
Dense Cataract: 1,532m/s
Pseudophakic: 1,532m/s

■ Vitreous ultrasound velocity

Normal: 1,532m/s

(In case of sectional velocity)

Pseudophakic: 1,532m/s

■ IOL ultrasound velocity

Pseudophakic1: 2,718m/s Pseudophakic2: 1,049m/s Pseudophakic3: 2,200m/s ■ IOL thickness

Pseudophakic1: 0.8mm Pseudophakic2: 1.0mm Pseudophakic3: 0.8mm

- IOL Power Calculation Formulas
 - SRK II
 - SRK/T
 - SRK (SHOWA)
 - HOLLADAY
 - Hoffer Q
 - HAIGIS optimized
 - HAIGIS standard

Biometry probe

■ Type: Solid type

■ Fixation light: Enclosed in the probe

(Red LED)

■ Oscillator frequency: 10MHz

■ Tip diameter: 5.3mmØ (Concave)

■ Dimensions and weight: $8mm\emptyset \times 97mm/30g$

8.1.5 Main unit

• TFT LCD: 10.4 inch, color touch screen

● Dimensions and weight: W360×D427×H346mm/14kg

8.1.6 Power Source

● Voltage: AC 100-120V / 220-240 V

• Frequency: 50/60Hz

• Consumption power: Less than 80AV+15%

* Specifications and outlook of the unit will be modified for the improvement of the design.

8.2 Energy and Other Consumptions

8.2.1 Influences of ultrasound energy on the human body



■ This instrument shall not be used for any purposes other than ophthalmic application.

This instrument is primarily designed as an ultrasound diagnosis equipment for ophthalmic use.

Since, therefore, the instrument is set for the application of a very weak ultrasound energy to suit the application of this instrument, use it with a minimum extent of diagnosis and measuring time, in consideration of the general precautions for ultrasound diagnosis and measurement equipment.

8.2.2 Ultrasound Energy

Application(s): B-Scan

			Ispta.3	Isppa.3	
	Acoustic Out	MI	(mW/cm2)	(W/cm2)	
Pre-Amendm	ents Maximum A	0.23	17	28	
Global Maxir	num Value		0.22	0.45	20.72
Associated	Pr.3(Mpa)		0.55		
Acoustic	W0(mW)			0.00143	0.00143
Parameter	fc(MHz)		10	10	10
	Zsp(cm)	Zsp(cm) Beam x-6(cm)		3.2	3.2
	Beam			0.095	0.095
	dimensions	y-6(cm)		0.083	0.083
	PD(usec) PRF(PRF)		0.250		0.250
			22		22
	EBD Az.(cm)			1.06	
		Ele.(cm)		1.06	

Application(s): A-Scan

	MI	Ispta.3	Isppa.3		
	IVII	(mW/cm2)	(W/cm2)		
Pre-Amendme	Pre-Amendments Maximum Acoustic Output				28
Global Maxim	num Value		0.12	0.02	3.75
Associated	Pr.3(Mpa)		0.22		
Acoustic	W0(mW)			0.000466	0.000466
Parameter	fc(MHz)		10	10	10
	Zsp(cm)		2.0	2.0	2.0
	Beam x-6(cm)			0.248	0.248
	dimensions	y-6(cm)		0.335	0.335
	PD(usec) PRF(PRF) EBD Az.(cm)		0.169		0.169
			30		30
				0.4	
		Ele.(cm)		0.4	

Application(s): Biometer

	Acoustic Outp	MI	Ispta.3 (mW/cm2)	Isppa.3 (W/cm2)	
Pre-Amendme	ents Maximum A	0.23	17	28	
Global Maxim	num Value		0.15	0.77	13.05
Associated	Pr.3(Mpa)		0.39		
Acoustic	W0(mW)			0.00436	0.00436
Parameter	fc(MHz)		10	10	10
	Zsp(cm)		2.0	2.0	2.0
	Beam x-6(cm)			0.101	0.101
	dimensions	y-6(cm)		0.117	0.117
	PD(usec) PRF(PRF)		0.269		0.269
			360		360
	EBD Az.(cm)			0.4	
		Ele.(cm)		0.4	

MI: the Mechanical index

Ispta3: the derated spatial-peak temporal-average intensity. Isppa3: the derated spatial-peak pulse-average intensity.

pr.3: the deratad peak rarefactional pressure.

Wo: the ultrasonic power fc: the center frequency

Zsp: the axial distance at which the reported parameter is measured. x-6, y-6: are respectively the in-plane(azimuthal) and out of plane (elevational)

-6dB dimensions in the x-y plane where Zsp is found

PD: the pulse duration

PRF: the puls repetition frequency

EBD: the entrance beam dimensions for the azimuthal and elevational planes

Acoustic output reporting table (IEC60601-2-37)

Index label		MI		TIS		
index label				Scan	$Non-scan(Aaprt \leq 1 cm^2)$	
				Biometry	B-scan	Biometry
Maximum index	x value		0.22	0.15	0.619×10^{-3}	0.824×10^{-3}
	pr, α [Mpa]		0.55	0.39		
	P [mW]				0.0130	0.0173
	Min.of [P α (zs),Ita, α	γ (zs)]				
Associated	Zs					
acoustic	zbp					
parameters	Zb					
	Z at max.Ipi, α [cm]		3.2	2.0		
	deq (zb)					
	fawf [MHz]	10	10	10	10	
	Dim of Aaprt [cm]	X			1.06	0.4
		Y			1.06	0.4
Othor	Td [us]		0.188	0.269		
Other information	Prr [Hz]		7722	360		
Information	Pr at max.Ipi [MPa]	1.67	0.78			
	deq at max.Ipi					
Operating	Ipa, α at max.MI [W/ cm2]		16.31	13.05		
control conditions	Control		※ 1		% 1	

※1 : All of 6 ring transducers transmit simultaneously.

α: ACOUSTIC ATTENUATION COEFFICIENT

Aaprt: -12dB OUTPUT BEAM AREA

Deq: EQUIVALENT APERTURE DIAMETER deq: EQUIVALENT BEAM DIAMETER fawf: ACOUSTIC WORKING FREQUENCY

*I*pa: PULSE-AVERAGE INTENSITY

Ipa, α : ATTENUATED PULSE-AVERAGE INTENSITY

*I*pi: PULSE-INTENSITY INTEGRAL

 I_{pi}, α : ATTENUATED PULSE-INTENSITY INTEGRAL

MI: MECHANICAL INDEX P: OUTPUT POWER

 $P\alpha$: ATTENUATED OUTPUT POWER

*P*r: PEAK-RAREFACTIONAL ACOUSTIC PRESSURE

Prr: PULSE REPETITION RATE

TIS: SOFT-TISSUE THERMAL INDEX

 t_d : PULSE DURATION

X,Y: -12dB OUTPUT BEAM DIMENSIONS

z: DISTANCE FROM THE SOURCE TO A SPECIFIED POINT

*z*b: DEPTH FOR *TIB*

*z*bp: BREAK-POINT DEPTH

 $z_{\rm S}$: DEPTH FOR *TIS*

8.3 Noises

This instrument makes noises in the following processes of operation.

- When turning the power on.
- When self-diagnosing.
- When starting to print.
- When pressing various keys.
- When measuring (such as taking measurement data).
- When inserting and recognizing the completion of insertion of the memory card
- When data transfer is completed
- When errors occur.

8.4 Applicable Standards

- IEC60601-1:1988
- Amendment1:1991
- Amendment2:1995
- IEC60601-1-2: 2001
- IEC60601-2-37: 2001

Appendix

Electromagnetic guidance

Caution: Medical electrical equipment.

EMC (Electro Magnetic Compatibility) must be considered before any medical electrical equipment is installed or put into service. Follow the information in the accompanying documentation when installing and operating the **UD-6000**.

Caution: Portable or mobile RF communication equipment can effect Medical Electrical equipment.

Guidance and manufacturer's declaration electromagnetic emissions

Table 201

The **UD-6000** is intended for use in the electromagnetic environment specified below. The customer or the user of the **UD-6000** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The UD-6000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The UD-6000 is suitable for use in all establishments, including domestic establishments and those directly connected to the
Harmonic emissions IEC 61000-3-2	Class A	public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration electromagnetic immunity

Table 202

The UD-6000 is intended for use in the electromagnetic environment specified below. The customer or the user of the UD-6000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ Burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UD-6000 requires continued operation during power mains interruptions, it is recommended that the UD-6000 is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

Table 204

The **UD-6000** is intended for use in the electromagnetic environment specified below. The customer or the user of the **UD-6000** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the UD-6000 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V rms 150kHz to 80MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF	3 V/m	3 V/m	d = 1.2 80 MHz to 800 MHz d = 2.3 800 MHz to 2.5 GHz
IEC 61000-4-3	80MHz to 2,5GHz	J V/III	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note1: At 80MHz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **UD-6000** is used exceeds the applicable RF compliance level above, the **UD-6000** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **UD-6000**.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the **UD-6000**

Table 206

The **UD-6000** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **UD-6000** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **UD-6000** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m					
W	150 kHz to 80 MHz 80 MHz to 800 MHz		800 MHz to 2.5 GHz			
	$d = 1.2\sqrt{P}$	d=1.2	d =2.3			
0.01	0.12	0.12	0.23			
0.1	0.38	0.38	0.73			
1	1.2	1.2	2.3			
10	3.8	3.8	7.3			
100	12	12	23			

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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